



Food Safe Pro! L1 User Manual

The complete guide to getting the most out of Food Safe Pro! L1!

As you go through Food Safe Pro!™ L1 we recommend that you keep a copy of the user manual available, it includes the “before you start” section, step by step instructions, and advice on how to get the most out of Food Safe Pro!™ L1 as well as refresher HACCP training, definitions, and much more!



The Home of We R Food Safety and Food Safe Pro!TM

Welcome to Food Safe Pro!TM

Congratulations and thank you for purchasing Food Safe Pro!TM

You will find your product registration number on your receipt and on the inside cover of your DVD, for downloads it is also your receipt number. If you have any questions or can't find your product registration number please email foodsafepro@werfoodsafety.com

This user manual is broken down into several sections, we recommend you explore it, there is a lot of useful information!

Before you get started we strongly recommend that you fill out the flow table that is attached. You will also want to have access to your company logo, any supporting documentation you use, (preferably on your computer in the form of a PDF or word document), and your current food safety program.

Food Safe Pro! is a very powerful tool that you will use to help design and implement your food safety program. To maximize its functions you need to have a very firm grasp of HACCP and your establishment's process. If you are unfamiliar with HACCP or haven't had any refresher training in a while we recommend that you read over the HACCP refresher module that is in this user manual before you start entering your food safety information.

To fill out the flow table form please print the form (found in the "Before you Start!" section) and then walk your processes, this means identify the different process steps that you take to manufacture your products, you can skip this if you already have a HACCP Plan. We recommend that you start at your receiving dock and work your way to your shipping dock. You want to identify every step in your process. Later you will consolidate these however each step and location will be entered into Food Safe Pro!TM (FSP!); this will allow you to create a flow diagram to be used in sampling and other modules in the program. An example is attached.

As you navigate your way through Food Safe Pro!TM the help system is available by left clicking the "?" button, more detailed help is available by right clicking the "?" button. You can turn the help system off at the top of the screen when you no longer need it.

Again, thank you for purchasing Food Safe Pro!TM !

Sincerely

Andrew A Lorenz

Andrew Lorenz, Senior Consultant
DND & Associates Consulting Group LLC
We R Food Safety!



Food Safe Pro! L1 User Manual (6V22S20132)

Table of Contents

Before you Start!.....	6
EXAMPLE Facility Flow Table:	6
Blank Facility Flow Table:	9
Section 1 General Overview of Food Safe Pro!.....	10
FSP! Spell Checker:.....	11
Document Library:	11
FSP! and Security:	11
Key Point to using FSP!:	13
How to duplicate a HACCP Plan (or other plans in FSP!)	14
Definitions:.....	14
Integrated Food Safety Program.....	14
HACCP Plans:.....	14
Verification Actions:.....	14
Validation:.....	15
Sanitation Standard Operating Procedures (SSOPs):.....	15
Food Safety Programs-Individual (includes GMPs, Ancillary SSOPs, Prerequisite programs, and Preventive Controls):.....	16
Under both the FDA and USDA these are the programs that are used to support the HACCP Plan. They all tend to address one issue each, see below for specific details concerning them.....	16
Good Manufacturing Practices (GMPs):	16
Prerequisite programs (Pre-Requs):	16
Preventive Controls (PCs):	16
Ancillary SSOP's:.....	17
Food and Drug Administration Food Current Good Manufacturing Practices (FDAFCGMP):	17
Animal Feed Current Good Manufacturing Practices (AFCGMP's):.....	17
Recall Management:	17
Allergen Control Program:	17



The Home of We R Food Safety and Food Safe Pro!™

RTE/LM Program:	17
Product Trace-Back:	18
Food Defense Plan (FDP):	18
Humane Handling (HH):	18
Poultry Good Commercial Practices (PGCP):	18
Plant Operation Controls:	18
System Alerts (SAs):	18
Sampling:	19
System Administration:	19
Printing Menu:	19
System Help & Support:	19
Designing a food safety program.	19
Getting started:	19
To think about:	19
Starting with sanitation:	20
Working with your individual food safety programs, GMPs, prerequisite, ancillary SSOPs, and preventive control programs:	20
Getting into the HACCP Process:	21
Getting started with Verification tasks:	22
Working with corrective actions and unforeseen hazards:	23
Validating your process:	23
Initial Validation:	23
Working with ongoing validation:	28
FDA Food CGMPs:	29
Animal Feed CGMPs:	29
Getting started with Allergen control:	29
Getting started with RTE/LM control:	30
Getting started with Product Trace Back:	30
Getting started with Food Defense:	31
Getting started with Humane Handling:	31
Getting started with Poultry GCP:	32



The Home of We R Food Safety and Food Safe Pro!™

A note about medical residues and antibiotics.	32
Reassessing your Food Safety Program	33
Reassessment.....	33
Reassessment at six months:	33
Printing:.....	33
Product Trace-Back in depth:.....	34
Figure 1 Receiving record:	35
Figure 2, batching record:	36
Figure 3 Shipping Record:	36
Figure 4 Inedible record:	37
1.Recieving.....	37
2.Batching	38
3.Shipping	38
4.Spillage/waste	38
5.Operations	38
Step by Step instructions:	39
Registration:.....	39
SSOP:	40
Food Safety Plans:	41
GMPs:.....	41
Prerequisite Programs:	42
Preventive Controls:.....	42
Add a Ancillary SSOP:	43
HACCP:	43
FDA Food CGMPs:	48
Animal Feed/Feed Plant GMPs:	49
Allergen Control:	50
RTE/LM Program:	51
Food Defense:	55
Humane Handling:	55
Poultry Good Commercial Practices:	58



The Home of We R Food Safety and Food Safe Pro!™

Product Trace Back:	60
Recall Management:	61
System Administration:.....	62
Food Safety Validation:.....	62
Refresher HACCP Training for FSP! L1.....	65
So what is HACCP?	65
HACCP PRINCIPLES	65
Preliminary Steps to utilizing HACCP:	65
Assemble the HACCP team, including one person who is HACCP-trained.	66
Describe the product and its method of production and distribution; identify the intended use and consumers of the products.	66
Develop and verify process flow diagram(s).....	66
PRINCIPLE I: CONDUCT A HAZARD ANALYSIS	67
1. Biological Hazards	67
2. Chemical Hazards.....	67
3. Physical Hazards.....	68
Radiological Hazards:	68
PRINCIPLE II: IDENTIFY THE CRITICAL CONTROL POINTS	69
PRINCIPLE III: ESTABLISH CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT	69
PRINCIPLE IV: ESTABLISH MONITORING PROCEDURES	70
PRINCIPLE V: ESTABLISH CORRECTIVE ACTIONS	71
PRINCIPLE VI: ESTABLISH RECORDKEEPING PROCEDURES	73
PRINCIPLE VII: ESTABLISH VERIFICATION PROCEDURES	74
Practical exercise: Let's get started!	76
The key point to remember with HACCP:.....	79



Before you Start!

Below is the example of a facility flow table, an example of a flow diagram, (don't worry, FSP! will help you generate a flow diagram), and a blank chart for you to use to help identify the steps in your process. This is critical as you will need this information to properly design your food safety program. Fill out the blank chart and you are ready to get started!

EXAMPLE Facility Flow Table:

Facility Flow Table

Facility Name: We R Food Safety Sausage Plant_ Date Completed: 01/01/2013

By: Mr. Andrew Lorenz

- Step 1 Receiving Raw Ingredients
- Step 2 Receiving Packaging Material
- Step 3 Store Packaging Material
- Step 4 Receiving Spices
- Step 5 Store Spices
- Step 6 Store Raw Ingredients
- Step 7 Thaw Raw meat
- Step 8 Cut up meat
- Step 9 Chop meat in bowl chopper
- Step 10 Grind meat, fruit, and vegetables
- Step 11 Mix ground product with pre-made spice mix
- Step 12 Stuff into casings
- Step 13 Package raw sausage
- Step 14 Store raw sausage
- Step 15 Ship raw sausage

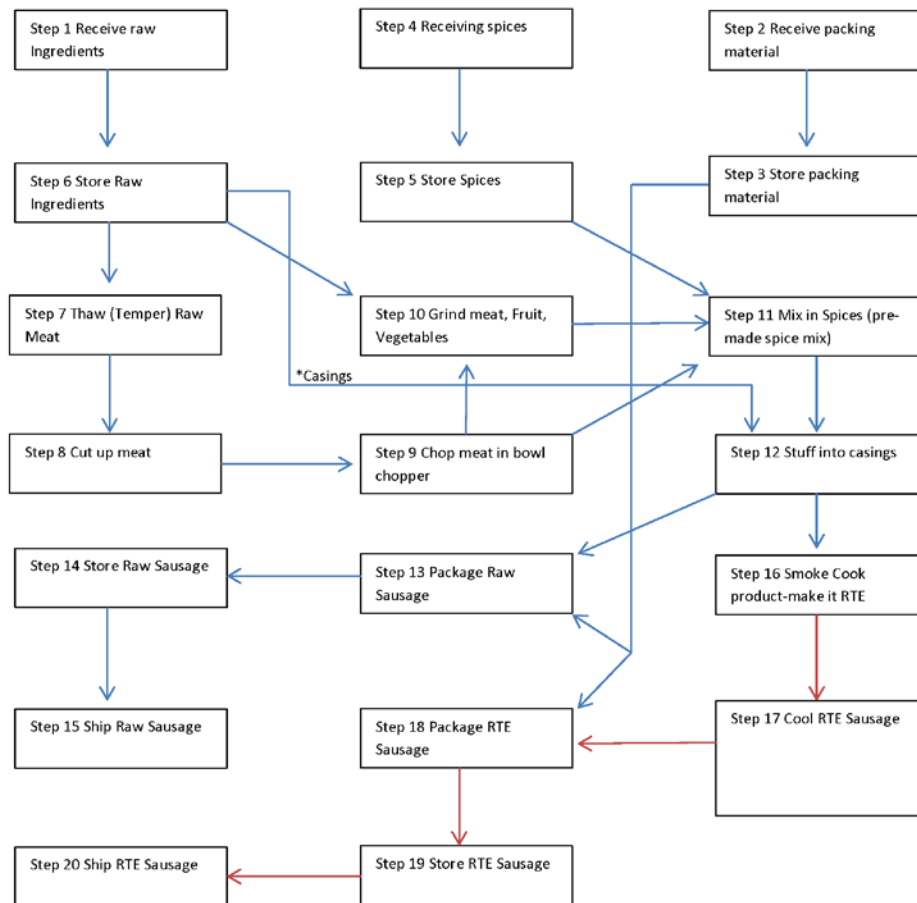


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Step 16 Smoke/Cook Sausage (RTE)
Step 17 Cool RTE Sausage
Step 18 Package RTE Sausage
Step 19 Store RTE Sausage
Step 20 Ship RTE Sausage



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Blue flow lines annotate raw products, red flow lines annotates product that has been cooked. Step numbers don't necessarily follow each other, that is the purpose of the flow lines to show how everything flows through your process, while it can become confusing it also is critical to determine the relationship of your potential hazards, for example your packaging material and cooked product come together, how do you know LM isn't being brought in on your packaging material? This is an example and is missing steps from the normal sausage production flow.



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Blank Facility Flow Table:

Facility Name: By:

Date Completed:

Step 1	
Step 2	
Step 3	
Step 4	
Step 5	
Step 6	
Step 7	
Step 8	
Step 9	
Step 10	
Step 11	
Step 12	
Step 13	
Step 14	
Step 15	
Step 16	
Step 17	
Step 18	
Step 19	
Step 20	
Step 21	
Step 22	
Step 23	
Step 24	
Step 25	
	If needed please use a blank piece of paper to add additional steps.



Once you have your flow table filled out, you are ready to start the software and get started building your food safety plan!

As mentioned earlier you will use the information that you have gathered to identify your process steps, you will put them into FSP! in the HACCP module and will then analyze each process step for hazards. After each process step has been added you can create your flow diagram. There is more specific help for this later in this document.

Section 1 General Overview of Food Safe Pro!

If you haven't developed a HACCP Plan before we strongly encourage you to develop a step by step process flow of production at your facility that is identified in the "Before you Start!" section, it will help you as you go through the program as described earlier in the manual.

You will also want to have a firm grasp of the things that have or can go wrong with your food safety program, FSP! Is only as good as the information you put in!

We have developed FSP! in a "modular" format. You can navigate between your different modules, or food safety programs using the left hand screen. Each Module is set up to run a bit differently, intuitively based on the subject area.

The final master output is the decision document. This document captures everything you have entered into the program except your Food Defense and Validation plans and is very useful when dealing with regulators, training new employees, and for giving you a good, in-depth review of what exactly your food safety program calls for. You can print the Food Defense and Validation plans from the print menu under system forms.

You will have several printed outputs, the decision document, your hazard analysis, and your HACCP Plan to name a few. We recommend that you print them out individually or to print them all print the decision document. Please be aware though that if you decide to print the decision document you will have a very large document! When you print a document it will open as a PDF that you can print or save. We recommend that if you are not doing FSP! L2 that you save these documents to a thumb drive or some other media that you keep offsite. Please note that the Recall plans for FDA and USDA are opened and modified in the recall module and that they go straight to the printer. This will be changed in the next maintenance update. (7/25/2013)



FSP! Spell Checker:

FSP! comes with a basic spell checker. The spell checker will work in text fields within the program. It's a very basic spell checker however it can "learn", when it comes up with a word that it doesn't know just click add and it "remembers" the word. With the acronyms and proprietary systems being used in food safety taking time to educate (by "adding") the program you will save a lot of time down the road.

Document Library:

FSP! comes with a set of folders that contain FSIS, USDA, OSHA, etc. regulations. They are current as of the date the software was saved to ship to you. You can either access them through FSP! on the main page or navigate to them using your file manager to point to the where you saved FSP!, then under the database folder you should point to either regulatory resources, scientific support, or supporting documents. As you link your supporting documents to the program copies will be saved to these folders. Remember the house in the top left is your home button, clicking it takes you to the main screen.

FSP! and Security: To use FSP! L1, you will create your own user name and password. You will then be able to administer the user name and passwords of others that you wish to give access to. In FSP! L1 user names and authority delegation isn't active, ie anyone can set up and sign. In order to maintain compliance with FDA and USDA electronic record keeping requirements there are a few things that you have to do.

1. Verify that the people whom you give access to FSP! are actually who they say they are. In the regulations the Government requires that you verify the "biometrics" of the user, this means that you have visual proof that the person whom you are giving access to is who they say they are. Generally 2 forms of picture ID are sufficient.
2. That you enforce a strict security policy; no one should share passwords. Each user must have a unique user name and password. You must have a written policy about information security that clearly states that passwords are not to be shared. In addition, FSP! includes IT security as part of the Food Defense Plan.
3. To insure integrity of your system, depending on the system you use, you can purchase a program that will lock the clocks on your computer. However, because we don't believe that purchasing additional software makes sense you can also just set your computer clocks to use internet time. We are also building a free update feature that runs in the background. FSP! will "ping" our servers and the national clock and will use the "official time" (NIST) to record dates and times. By using the NIST NTP (Network Time Protocol) to time/date stamp your signatures and entries, you meet Title 11 requirements for data



- integrity. In the event that you don't have an internet connection the system defaults to using your computer's internal clock; FSP! will detect that there is a difference between your computer clock and the "official time". It will then notify you so that you can update your internal clock. This update is expected to be published in late summer and will be provided to all customers free of charge as part of the normal maintenance update. As part of your policy you must address the accuracy of your computers clocks, ie that they are set up and are not changed without authorization; failure to implement and enforce this policy will result in the failure of FSP! to meet Title 11 requirements.
4. Accounts for "Guests" should only be given read only access (This is not functional in FSP! L1, to give read only access you must save the plans in PDF format by printing them from the print menu and then opening them outside the program).
 5. For FDA only: If the current proposal for Title 11 is passed you will need to submit a certificate to FDA Office of Regional Operation (HFC-100), 12420 Parklawn Drive, RM 3007, Rockville, MD 20587 that includes the user, name, and hand written signature. At this time it is not necessary to do so (as it is not a legal requirement)
 6. Passwords need to be periodically updated to maintain security.
 7. FSP! data is encrypted in such a way that the data itself is not readable outside of the program, ie even if someone were to get a copy of your data without password access they will not be able to access the data, again the emphasis is on protecting your passwords!
 8. Strong passwords are those that are not easily discernible but are easy for you to remember. Using family names or birthdays are not strong passwords. "FoodSafePro" is not a strong password as if someone is trying to break into Food Safe Pro! they will likely figure it out. Using something like: 05Ab01cD2013 creates a password that is very hard to break, however it is sequence based so there is some vulnerability. If you study it you will determine that it is a date, May 1, 2013 with the abcd used in a sequence, starting and ending with capital letters. One way to make it stronger is to add unique characters, such as !, @, #, \$, %, ^, etc. If you add them to the front and back the password becomes much stronger and still lets you have something you can remember, for example if you set your password on the date you saw your first live concert and used this method you might have a password like this: !07Ab23cD1973@. Six months from now when you need to change your password you can pick the date of the next concert you saw and move everything else up, so you end up with something like this: #11eF14Gh1973\$ it's very hard to figure out however you as the owner of the password will always remember the dates (July 23, 1973 and November 14, 1973), and you will also remember the sequences. Again, using anything that is not totally randomized creates vulnerabilities however whatever method you use needs to be 1-Strong and 2-easily remembered!



Something to keep in mind is that if you use FSP! to create your plans, and then print them, and then sign them you are exempt from the title 11 requirements, the printed and signed copies are the official documents of record. Many people want to have a single place where everything is and FSP! meets that need regardless if it is the sole repository of your information or if it is the interface tool just used to create you food safety program.

Key Point to using FSP!:

One of the keys to using FSP! is to take your time and get the right data in. Government regulators want to see what your thought process was when you designed your program. In FSP! you will capture that information as you enter data into the applicable fields, we recommend that you share your decision document with them along with the hazard analysis and HACCP plans themselves. The decision document is extremely large, we recommend that it be shared electronically and NOT printed as a typically establishment with 4 HACCP Plans can have over 500 pages in the decision document. In the next maintenance update we are going to give you the option of turning off portions of FSP! that you don't use, for example Animal Food.

If you already have a written food safety program and just want to "get it into the software" you can copy your information directly into FSP! to quickly generate your documents by copying and pasting the text and then attaching supporting documents. You can also contact us about our data entry service.

There are several resource folders that load with FSP! L1, regulations and blank forms are things you will find very useful. Please be aware that in L1 these folders are not updated, if there are changes to regulations you will have to be aware of them and load them into your program as applicable.

On the main screen there are links to the FSIS export library, the We R Food Safety! web site, the support site for FSP!, and scrolling links to our allied businesses and organizations-this can be turned off.

FSP! modules are integrated with each other, the same as your food safety program. For example you may have a pre-requisite program for receiving raw material. It's your own good manufacturing practice, you use it for a lot of reasons, to make sure your inventory is correct, that you are receiving what you order, etc. FSP! lets you link this program to others, such as trace back, recall management, you hazard analysis, etc.

When you are working in the HACCP module there are a couple of things to keep in mind. Until you sign the HACCP Plan it is in draft mode. When you sign a HACCP Plan it becomes active, this is the plan you are using in the plant. As soon as you modify an active plan a copy becomes a draft. An additional copy is made and is moved into the Archive File and cannot be modified, it is read only. This helps you meet the record keeping requirements of the USDA and Title 11 requirements of the FDA. You will be able to have a clear concise audit trail of your documentation and it is also maintained in PDF format that is



locked to prohibit changing historical records. Please note that archived records are “locked” in such a way that they CANNOT be unlocked. This insures the integrity of your data. If you find a glaring typo after you have set your plan to active in your reassessment area identify the reason, i.e. reassessment to correct typo XYZ. As your regulator reviews your plan it is clear why you made the change and you are not in noncompliance as you found and corrected the issue. **We cannot emphasize enough that if you archive without keeping an active plan or duplicating the plan you will have to reenter everything, there is no way to unlock the data once you have archived it!**

How to duplicate a HACCP Plan (or other plans in FSP!)

When you wish to modify an active plan open the active plan list and double click on the active plan you wish to work with. You will receive a pop up window that asks if you wish to archive or duplicate. WARNING, if you select Archive you cannot undo this change. To modify select duplicate and check the box to keep active. You will then have a draft plan to work on while your plan remains active. When it is time to start using the active plan sign it and click save, then double click the old plan and select Archive.

Definitions:

Integrated Food Safety Program is defined as: The HACCP plan in operation including the hazard analysis, the supporting documentation including prerequisite programs, GMPs, Preventive Controls, etc. used in supporting decisions in the hazard analysis, HACCP and other records. In other words, everything you do to make a safe product for the consumer!

HACCP Plans: Hazard Analysis Critical Control Point. This is the frame work your food safety program is built around. To simplify it, you are going to use HACCP to create your food safety program. You do this by taking all the parts of what you do and analyze them together to figure out where something could go wrong, and use HACCP to help you fix it before it breaks. When you create your HACCP Plan you will go through a wizard process that helps make sure you haven’t missed anything. It asks questions and you have to enter data to help you not just formulate your food safety program to identify and control hazards but it helps make sure you are meeting all the regulatory requirements that your government inspectors and auditors are looking for.

Verification Actions: These are the actions that you take to verify that your program is working as designed. In FSP! L1 and L2 the menu on the left is turned off as these are used to input data in L3 and L4. You will designate your verification activities in your HACCP Plans as you go create your HACCP Plan. In L3 and L4 these modules are turned on and give you greater control.



Validation: Validation is the act of designing and testing your system to make sure that you produce a safe product by controlling potential food safety hazards. Both the USDA and FDA have documents about validating that are available in the resource folder in Food Safe Pro!. Validation starts when you start designing your system because as you look at your system, identify hazards, develop controls, etc. you are in fact reviewing scientific support and your experience against what you can and cannot do. Those documents are the basis for your validation plan. There is more detailed information concerning validation later in this document and in the resource folder. Some of the key points you need to be aware of immediately are that when you select supporting documents they need to be as close to your actual process as possible. Selecting a scientific study about protozoa survival in the ocean when you are worried about mold growth on beef jerky doesn't pass the common sense test. Some good sources of information are compliance guidelines, and to a lesser extent, peer reviewed journal articles, challenge studies, subject matter experts, and modeling programs. Please be cautious when using journal articles, they need to mirror what you are actually doing and in many cases they do not. That is not to say that they are not helpful, they are, because they often point you in the right direction when you are trying to develop a control. Regardless of what you use to start off you need documents that match what you are doing, that demonstrate the typical bacteria load reduction, and that clearly state the operational parameters (those key things that have to be done) used to achieve the bacteria load reduction. If the study you are using matches your process very well, it describes the bacteria load reduction (Specific pathogens that you are addressing), and has clearly defined operational parameters you may not need to do additional laboratory testing however very often the scientific support you have won't be this clearly defined. In the case were you don't have clearly defined scientific support you will need to put together your own validation document. It may include a computer modeling program for bacteria, several scientific documents that closely match your process, laboratory testing for the pathogens (or in some cases indicator organisms), in house testing of critical parameters (such as temperature, PH, water activity, pressure, etc.), and possibly subject matter expert specific statements or guidance. Remember to identify what critical operating parameters that you are validating in your validation protocol!

Sanitation Standard Operating Procedures (SSOPs): These are the basic sanitation practices you use routinely throughout your facility, for example how often you clean your floors, walls, etc. In essence your SSOP gives you the basics for making of sure your level sanitation, before and during operations, are sufficient to keep you from producing an adulterated product. They often overlap with the FDA's CGMP's; in many ways the SSOP is your basic sanitation foundation, it is what you are going to use to build your food safety program. Without basic sanitation it doesn't matter what you do, your risk of producing an adulterated product is extremely high!



Food Safety Programs-Individual (includes GMPs, Ancillary SSOPs, Prerequisite programs, and Preventive Controls):

Under both the FDA and USDA these are the programs that are used to support the HACCP Plan. They all tend to address one issue each, see below for specific details concerning them.

Good Manufacturing Practices (GMPs): These are the Good Manufacturing Practices that you have developed for your establishment and production. Often they don't have the intense record keeping requirements that HACCP records. They often support that you don't have a hazard, for example if your receiving GMP states that you reject any product with Allergens the likelihood of you having an Allergen issue is very remote, when used to support decisions in the HACCP system they need to be supported and validated; this includes record keeping. As mentioned earlier they typically don't have the intense record keeping requirements of HACCP records however they do require sufficient records to demonstrate that they are being done in order to support the decision in the HACCP Plan.

Prerequisite programs (Pre-Requs): are programs that you utilize much like a GMP however they typically are customer driven and are related to quality issues more than food safety issues. However, they can and do have an impact on your food safety program, and can influence decisions you make in your hazard analysis. Much like GMP's, they typically don't have the intense record keeping requirements of HACCP records, but they do require sufficient records to demonstrate that they are being done in order to support the decision in the HACCP Plan.

Preventive Controls (PCs): **USDA** Preventive Controls, again, these are very similar to GMP's however they typically are used together to form a multi hurdle approach to control food safety hazards. An easy way to think about them is that they don't meet the criteria to be able to control a hazard in the HACCP Plan however they have a greater impact on food safety than a GMP. Unlike GMP's they typically do have the intense record keeping requirements of HACCP records. **FDA:** Something to keep in mind is that the FDA uses the term Preventive Control to describe what you do at Critical Control Points in your HACCP Plan. This is a bit different than how the USDA views them. If you are a FDA inspected establishment your Preventive Controls will be the equivalent of your CCP's. The way the FDA looks at it is that you perform your hazard analysis and then develop preventive controls for the hazards you identify. This is just another way of saying you perform a hazard analysis and identify controls at those critical points in your process. In FSP! we recommend that you utilize the HACCP process fully utilizing the system, i.e. developing CCP's, monitoring, etc. and use the GMP's, Prerequisite Programs, and then develop Preventive controls for anything you haven't already addressed such as multi-hurdle approaches used to control Salmonella.



Ancillary SSOP's: These are SSOP's that are created to address a specific issue, for example condensation in the smoke house, or how to clean the buffet line during high volume service, or maybe how to clean out the seeder after using a coated seed to plant. They have the same record keeping requirements as your standard SSOP's. You will often use them to address specific sanitation issues that have the potential to affect food safety.

Food and Drug Administration Food Current Good Manufacturing Practices

(FDAFCGMP): These are things you are required to do by the FDA. In many cases they overlap with your Sanitation Standard Operating Procedures (SSOP) and your GMP's. We have set up FSP! to allow you to put those that you have added additional information to into a GMP, those that you don't specifically want to have extra writing about are still in the program so you can accept them the way they are. There is also a self-audit included that you can use to perform self-audits to verify that you are meeting all of these requirements.

Animal Feed Current Good Manufacturing Practices (AFCGMP's): These are the Current Good Manufacturing Practices used by animal food manufacturers and include medicated and non-medicated feed manufacturing. They are similar in scope to the FDA Food CGMP's, in many cases the GMP's that you already use will address the concerns that the AFCGMP's address.

Recall Management: Here you will design your recall plan. You will be able to input the key people you need to contact. Depending on who regulates you the requirements between USDA and FDA are sufficiently different that we developed two separate plans. You can either accept and use the plans we have developed or upload your own plan. Even if you accept the plans we developed there is an area for you to add additional information. The FSP L3/L4 module is turned off in L1 and L2; it automates the recall process dramatically.

Allergen Control Program: The FSP! Allergen program helps you identify when you verified your labels, gives you the ability to attach your GMPS and SSOPs that address how you operate in reference to Allergens, and provides you a self-audit that you can use to assure that you are following your program and minimizing your risk of an allergen related incident.

RTE/LM Program: Ready to Eat/Listeria Monocytogenes program is based on the compliance guidelines developed by the USDA as well as the FDA. They are designed to flow along the same lines as 9 CFR 430 as this CFR covers all aspects of LM control, specifically in Deli products but is also very good at helping control LM in everything from Dairy products to Dog food to melons growing in the field. The gist of it is that based on how you make your products you determine what controls you will need, how often you will need to test for LM in product and in the environment. It also includes test and hold



procedures as well as validation procedures. The email alert system is not functional in L1 however it is available for L2, L3, and L4. Both FDA and USDA FSIS guidance documents are in the document library.

Product Trace-Back: The FSP! Trace-Back module helps you design a trace-back program that works. In the FDA arena many operators are receiving warning letters for failing to be able to trace-back and forward, the same is happening in the USDA arena. The FSP! program for L1 and L2 is paper based and allows you to generate the blank forms you need to implement it. In the L3/L4 versions trace-back is integrated with your inventory system and your recall management system resulting in rapid and accurate responses to issues. See the Trace-Back section later in this manual for more information concerning Trace-Back.

Food Defense Plan (FDP): The food defense plan in FSP! is very simple to design. You select the items that apply to you or add them in the text box, save, print, and implement, it's that easy!

Humane Handling (HH): We have broken the humane handling portion into three main parts. The first is the pre-planning phase; this is where you will answer a series of questions, after you have completed answering the questions you then review your current plan and make any necessary changes. The next phase of FSP! humane handling is where you will enter your actual plan; it includes the ability to upload documents to support the different features of your plan and also gives you the ability to set a frequency of self-audits. The third part is a self-audit checklist. Unlike many other checklists it is not scored (it is pass or fail), the purpose of the checklist is to review your program with the intent to find ways to improve the program, without wasting a lot of time. If you wish to use a scored checklist there are several available by using Bing or Google search engines to search the internet.

Poultry Good Commercial Practices (PGCP): The poultry good commercial practices incorporate your written program with a self-audit. As you go through the wizard you will be asked a series of questions, you select yes, or no and then make comments. The questions include recommend times or other industry standards. As you answer the questions the questions you are building your GCP's. After you have completed answering the questions your Poultry GCP's, they are ready to be implemented. There is also the self-audit form that you can use to make sure you are on track. It is very similar to what is used by FSIS.

Plant Operation Controls: This module is turned off in L1 and L2. In L3 and L4 it is where you manage your different systems such as inventory control, employee training, automated temperature checks, etc.

System Alerts (SAs): this module is turned off in L1 and is partially active in L2 (You can set specific reminders in L2 that are emailed or sent as a text message to whomever you designate). In L3



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and L4 it is where you manage your different systems alerts such as positives, deviations from critical limits, missed checks, failed checks, etc.

Sampling: This module is turned off in L1 and is partially active in L2. (You can set specific reminders in L2 that are emailed or sent as a text message to whomever you designate to take samples on dates you designate). In L3 and L4 it is where you manage your different sampling programs and the results of tests, review trend analysis, etc.

System Administration: in the system administration screen you administer FSP! by designating employee's, uploading your logo, setting permissions, determining your regulator and business type. You can also upgrade to L2 and see your current software information, etc. There are two tabs that are not functional in L1 and L2, the facility schematic is used to generate a detailed overlay that is integrated into the sampling (and other) modules. The database storage is used to show how much data you have on the server, locations connecting, users, etc. In L2, L3, and L4 your data is backed up on our main servers and also on our offsite servers as well as on your local computer giving you a high level of confidence that your data is secure, and safe!

Printing Menu: The printing menu is used to generate the "paper" copies that you print to either maintain locally, provide regulators, customers, etc. It is also where you generate your PDFs (Electronic format).

System Help & Support: system help and support is where you find out how to do something in FSP!, we have included training, help documents, etc. Please note with L1 these documents start getting old the minute we ship you FSP! as we don't provide updates, in L2, L3, and L4 we will keep these documents current utilizing our server.

Designing a food safety program.

What exactly is a food safety program, or as some people call it, food safety system? In short it is what you do to produce a safe product. In many (if not all) cases it has to be in writing and someone is going to check and see if you are following what you wrote down. Why is this important? Simple, don't create a monster in writing that you can't actually do on a day to day basis!

Getting started:

To think about:

To get started, what is it that you do? What do you make? How do you make it? Where do the raw material, the packaging material, and anything and everything that goes into your product come from? These are all questions that people try to start from, and in the end they all have to be answered



however the first question that you really need to ask is: How does food safety fit into our company? Is your company one that has a separate QA department that monitors everything, or is your company one where each production employee is responsible for monitoring food safety? Are you a very small shop where everyone has to do a lot of different things? In the end in order for a company to produce a safe product everyone from the top to the bottom has to buy in to the fact that food safety isn't a separate event or group of tasks, it is an integral and dynamic day to day part of what you do.

Once you figure out the answer to how food safety fits into your business culture you can begin to put together your food safety team. If you are a very small shop there might not be a team to help develop the plan, maybe they only have time to look it over. That's fine however we recommend that someone from all aspects of your operation be part of the food safety design team.

The next thing you have to do is realize that food safety falls into three realms: Scientific, Regulatory, and what can actually be done (or as a lot of people in the business say, Common Sense!). Science may tell you that you should do something, like test and hold every animal coming into the facility for medical residues. When you look at what you can actually do that isn't feasible, you will be out of business shortly. Regulatory says that you have to do something. So how do you reconcile these three dynamics? We wish we could say it was easy however it is not. FSP! will help you build a plan that addresses your regulatory requirements but it can't actually fill in the blanks. Putting the right information into the right place is up to you.

Starting with sanitation:

We recommend that you start with sanitation. Your Sanitation Standard Operating Procedures (SSOPs) are the basic foundation of your food safety program. Some of the things you need to consider are how often we clean our floors, walls, ceilings, overheads, equipment etc. How do we do it? What sanitizers do we use? You want your SSOP to be simple and easy to follow. If you create complex cleaning regimens your employees will often fail to follow them, keep them simple and easily implemented. Schedule when you are going to do your maintenance cleaning, such as hallways, ceilings, office spaces, etc. that you utilize in the facility as well as the production areas. You can have the cleanest processing room in the world however if your employees are walking through filth to get to them you have a potential cross contamination issue. If you are regulated by the FDA many of the basic sanitation operations are requirements. Use your SSOP to make sure that you are meeting those requirements!

Working with your individual food safety programs, GMPs, prerequisite, ancillary SSOPs, and preventive control programs:

The next area we recommend that you work on is your prerequisite programs, GMPs, Preventive controls, and ancillary SSOPs. These are programs that you do for a variety of reasons, such as multi-functional programs like receiving raw ingredients. You are primarily doing it to verify that you are



getting what you ordered however you also verify food safety issues such as there are no unknown (to you) allergens coming into your facility, that temperatures and product condition is acceptable, etc. You also collect information you may need in a trace back or recall situation. You may also have a program that is required by a customer that has minimal if no impact, but you still must do it (good example of a pre-requisite program) such as using a certain lot numbering system, requiring that you use hot water as a sterilizer instead of chlorine, or not producing pork and beef in the same facility. At this point you may have also generated some preventive controls. The easiest way to think of something that is a preventative control is the multi-hurdle approach. By themselves none of them have the ability to control the hazard however when put together they can have a major impact on the potential hazard. Be careful when designing preventive controls, the critical parameters can often be confusing resulting in identifying them as a CCP, if it is actually a critical control point address it in the HACCP Plan. You will typically develop an ancillary SSOP in response to a sanitation issue, for example condensation control. Another example might be that you need a specific clean out procedure after running a specific item, the ancillary SSOP is the type of program you will use, its specific in nature and addresses a sanitation issue that has an impact on the other programs and food safety.

Getting into the HACCP Process:

The next step is HACCP process. As you work your way through the module you will be asked questions, such as what products do you make, what is your process, etc. As you answer the questions and put your data in you will often make a determination that you don't have a hazard because of something you do. You will also relook at the SSOPs, GMPs, etc. and make changes, while it seems like a lot of work in the end it will pay a huge dividend in time saved. At the point you are making a decision as to the impact of your ancillary programs. Is it a GMP, something that you have in place that may impact on your ability to produce a safe product? Or is it a program you do for a customer that is strictly a quality control issue? Is it in fact a preventive control? For example if you have a metal detection program because of a customer requirement it may only be a pre-requisite program. However let's say the reason you have a metal detection program is because you have found metal particles in your product, it's in the realm of a safety concern however it doesn't rise to the level of a hazard that is reasonably likely to occur, now it's a GMP, one that reinforces that your decision that the hazard isn't reasonably likely to occur. Maybe you require your suppliers to run your raw material through a metal detector prior to you receiving it and that they have to send certification to that process. Now you have a preventive control. The preventive control again supports the decision that you don't have a hazard reasonably likely to occur-please keep in mind when dealing with Preventive Controls that the USDA and FDA have slightly different take on them.

As you go through and design your HACCP system remember that at most steps you won't be dealing with a hazard however you want to thoroughly explore each step for hazards. When you do come across a hazard you really have to put some time into designing the control. We will use metal



detection as an example. If you determined that at your trim step that metal contamination is a hazard likely to occur how you do handle it? Most people will put in a metal detector and say the critical limit is no metal in their product. The first time they find metal in product (because the metal detector is working) they now have a deviation from a critical limit. Instead had they said that their critical limit is that they utilize a functioning metal detector that is sensitive enough to kick out any meat with metal that is larger than 3mm, and that all trim passes through a metal detector; when the metal detector kicks out meat with metal in it they have a properly operating system. The critical limits will then be that all meat passes through the metal detector prior to packaging and that the system is operating as designed. It is monitored by an employee who verifies that all meat passes through it and periodically sends seeded samples through to verify that it is kicking out anything with metal above the 3mm size.

As you can see, how you design your program can have a huge impact on your day to day operations. Trying to deal with 5 deviations a day versus being confident that the product you are producing is safe allows everyone in the organization to focus on producing safe product. If you were busily running around trying to deal with those metal deviations instead of focusing on producing product what is the impact? Do you really have the time to waste? Putting the time in during your design and validation phases will pay huge dividends later on.

Getting started with Verification tasks:

What is verification? Simple, it's making sure you are doing what your program says you are going to do. You verify that people are monitoring correctly (by direct observation of them doing the task), timely, etc. You verify that your equipment is calibrated, you verify that records are properly filled out, and you verify corrective actions are done according to your plan.

As you set up your HACCP Plan if you develop a critical limit the system will walk you through developing verification tasks to include:

Direct observation:

Direct observation is not to observe what the employee is recording when they are doing a monitoring task, it is to verify that the monitoring is being done correctly.

Calibration of monitoring equipment:

Calibration of monitoring equipment is just that, you need to know that the value your equipment records is accurate so you need to determine how often you verify that it is accurate. We recommend that you use the manufactures recommendations when determining calibration frequency.

Records Review:

You review your records to make sure they are complete and that there are no errors. This includes missing monitoring or direct observation checks, deviations that the operator or monitor missed, etc.



Corrective Actions:

You verify that corrective actions are taken in accordance with your plan and that you haven't shipped product that is adulterated, contaminated, or is otherwise unfit.

Working with corrective actions and unforeseen hazards:

The same scenario plays out as you get to your potential corrective actions. If you have the proper design to your system you will not have many corrective actions, those that you do have will tend to be for something unforeseen. It is very hard to plan for something you didn't know was coming. We strongly recommend that you identify the regulatory requirements for corrective actions in your plan and then when something does happen utilize them as a process to correct whatever it was that happened. If you find yourself constantly redoing the same corrective actions over and over (I have seen "training" used so much that the many companies should be issuing Doctorate degrees!) you have a system issue that should be addressed, not a corrective actions issue. Our metal detection scenario is a good example, instead of performing corrective actions over and over you reassess your system and design it so that it prevents the hazard and is something that is doable. In the end you meet the regulatory requirements, minimize wasted time, and used good sound science to come to your conclusions.

Validating your process:

After you have addressed corrective actions and unforeseen hazards you need to sit back and really look at what you have designed to determine if it is valid. You are going to design a two part validation protocol for your system, an initial validation and ongoing validation. Please don't confuse these with verification. Too many people are afraid of validation, it takes time and effort and a lot of folks just don't want to do it. In addition to that, it's not well defined and validation has become a twisted mess in many places. Validation is actually very simple; is your system designed to produce a safe product by controlling potential hazards? You test your system to make sure that it does what it's supposed to.

As you designed your system you reviewed multiple scientific documents, spoke with subject matter experts, used your experience, etc. All of these documents are in truth the first part of validation. (Note, if you used experience make sure you documented your thought process and attach it as supporting documentation!)

For initial validation there are several parts, we will address them separately and then pull them altogether.

Initial Validation:

Initial Validation is typically done over the first 90 days of operation of the new or revised plan. If you have developed a completely new plan you will need to validate all parts of the plan, this includes your prerequisite programs, preventive controls, GMP's, and all HACCP components. If you have just made a



modification to an existing plan generally you only need to validate that portion of the plan that is impacted by the change.

The initial validation focuses on making sure that the critical parameters that you have identified are actually valid (or working to keep product safe) in your establishment and that the functions you use to monitor the plan are effective.

In the validation module you will select the plan and or step you wish to validate. You will enter the necessary information; at this point you sign and date it. This then becomes an active plan. You don't fill out the summary or findings until after the validation is complete; this typically runs approximately 90 days depending on your production. So you spend the next 90 or so days collecting data and then you review it. If there are no problems you will go back into FSP! and update that validation step by opening the active validation program and then completing the summary and the findings portions. Attach the records you generated and then sign and date it again. The plan now lists in the completed column. If something didn't work out you enter that also and make the changes to your plans and processes and then revalidate the changes following the same procedures. **WARNING:** Don't forget to capture what the critical operating parameters that you are validating are in your validation protocols, we recommend that you identify them in the first sentence!

Identifying a product for validation:

The USDA recommends that you identify one product from each HACCP category (Raw Not-Ground Process, Raw Ground Process, Fully Cooked Not Shelf Stable Process, Heat Treated Not Fully Cooked Process, Not Heat Treated Shelf Stable Process, Heat Treated Shelf Stable Process, Secondary Inhibitors-Not Shelf Stable Process, Irradiation Process, and Thermally Processed, Commercially Sterile Process) to gather in plant validation from. They recommend that you use the worst case scenario product, ie the most risky product. If all things are equal use the product that you produce the largest volume of. You want to take this product and show how your critical parameters are used and how they prevent the hazard. For example if you make a hot dog product it's considered high risk for *Listeria monocytogenes*. You have identified that the critical parameters for this product are the lethality temperature (160°F), and the proper implementation of your RTE program. When you do your initial validation you are going to perform a statistically valid number of tests to make sure your systems monitoring frequency is valid. (SQC is a great online tool to determine inspection frequencies; you can find a link on our website: <https://werfoodsafety.com/Services.html> scroll to the bottom of the page for the link). You are also going to validate your RTE program. If you are using strictly sanitation to control LM you will increase your checks, increase your sampling frequencies, etc. All too often someone tries to save a dime by only taking one or two samples and when one is positive they say it is an outlier, if you don't have statistically valid sampling plans your results, be they positive or negative, won't tell you what is actually going on, ie if your plan is valid or not. The other thing to consider is that if you are strictly following a FDA or USDA compliance guideline you are validating that you can implement that guideline, not if the guideline is valid. Many people use the guidelines and then turn around and waste money by revalidating the premises in the guideline instead of focusing on validating that they can implement the guideline.



Validation of frequencies. This is probably the easiest part of your program to validate. If you have continuous monitoring there is nothing to validate, the frequency is continuous right? The answer is maybe. You have to look at the critical operating parameters around whatever the process is, to include continuous monitoring and make sure you are meeting them. Let us use our metal detection scenario as an example. You have designed the system so the operator tests the metal detector with a metal see before product goes through and every four hours of operation after that, so basically three checks a day (Once before and twice during operations). The question is that enough checks a day to make sure that the CCP is under control? The reality is you can't afford to pay an employee to monitor the machine every five minutes, however you also can't afford to rework four hours of product. You have several options, you can do a statistical analysis based on the amount of product, operating time, etc. and increase your monitoring for the first 90 days. Another viable option is to use a regressive sampling protocol, for the first two weeks you check the machine every 30 minutes, for the next two weeks one time every 45 minutes, then the next two weeks, you check it every hour, the next two weeks you check it every two hours, the next two weeks you check it every three hours. You need to monitor system failures as you reduce the time between checks, you will notice that the first two checks only move 15 minutes. This is on purpose as it is building a lot of data for you to look at that is similar. At the end of the validation period you go back and you have no failures until three hours starts, 25% of those checks resulted in a failure. If this happens you can't support every four hours, it just doesn't make sense. You will then adjust your frequency to every two hour, or maybe you will put a calibration step in at every 2 hours? You will have to decide however the point is that the validation data gave you the information you needed to support your frequency. Another example is that you never had a failure, all those checks and nothing ever went wrong. You have supported your four hour check, you could even support less checks however keep in mind the financial impact if you only check one time a day and find out at the end of the shift the metal detector wasn't working, can you afford to rework an entire days production? These are the decisions you have to make!

Validation of Critical Limits: Validating critical limits can be a little more challenging. Why did you pick the critical limit in the first place? Is it a regulatory requirement? Is it based on a scientific document? Are you basing it on an in house challenge study? The purpose of the critical limit is to control a hazard, for example if you are cooking a meat product and are using FSIS regulatory guidance on how hot it has to be to get the log reduction you want your validation protocol is going to be pretty straight forward. You will upload a copy of the regulation, compliance guideline or other government document into FSP! and reference it in your decision. You will then determine that you are actually meeting the critical parameters that the reference calls for. For example if you have a smoke house and are using Appendix A the requirements aren't just time and temperature they include humidity. If you set your critical limit at 160°F for instant lethality yet fail to provide some sort of control for humidity you will be found to be noncompliant. Your validation of the critical limits needs to address all of the requirements that you are basing it on. (In your smoke house don't forget to validate your cold spots. Where are they? Do they change based on product?) Another example might be that you have a critical limit of maintaining product in a buffet line at over 140°F. How do you validate the 140°F is valid? As it



is a regulatory requirement you reference the requirement—it's the law, no challenge study needed. You do have to validate that your systems of monitoring and verifying are sufficient to demonstrate your system is in control. Another example is that you are basing your critical limit on a scientific document. You are spraying your product with a lactic acid to reduce the bacteria load. If you are a beef slaughter plant how can you validate that it really works in your establishment? One way might be to take a series of samples from the carcass as it moves through your system, you can start at the hide on station and test at different points throughout the process all the way to the cooler. Your data will show positives at the beginning and if the system is working, be negative by the time the carcass is in the cooler. If you just test the carcass as it comes out of the lactic acid cabinet you really don't know if the lactic acid is working or not, the carcass might have been negative before it enters the cabinet. When you match this data up with the other data you have recorded demonstrating that you meet the critical operating parameters such as sufficient pressure, proper temperature, etc., you can clearly demonstrate your system is valid. Another example is that you have a manufactures instructions that states that in order to dry the product you must reduce the water activity to less than .94 prior to grinding, this is your critical control for Salmonella. How do you validate that water activity of less than .94 works? Again, you can start testing product for moisture activity before the drying process starts and at points throughout the process for whatever it is you're focusing on. *Salmonella* will die out at water activity that is low enough however it can literally take years for that to happen! If you have a product that is very high in fat and very low in moisture, such as chocolate, or certain meat products you know that *Salmonella* is relatively resistant to drying and can survive on food production surfaces for some time; you may find through your testing that your process is too slow allowing the Salmonella to survive your process. The only way to know if your system is valid is to test it, ie validate it!

Validate the location of the CCP (or other control): Is the CCP in the right place of our process? In some cases it is a regulatory requirement, such as cooling, in others it is not so clear. If we have a lethality step and then put raw ingredients on after the lethality do we have an issue? Should there be two critical control points or should we move the CCP location? An example might be an ethnic dish that requires you to cook the meat portion, then add vegetables, sauces, and spices and briefly reheat. Is the CCP just the heating of the meat item, or is it a combination of heating the meat and then reheating the combined ingredients? Or maybe you heat the vegetables, sauces, and spices separately and combine them just prior to serving. Where is that critical control point really supposed to be? Initially you set the plan up with the CCP after you heat the chicken, however while that works for the chicken you find that your sauce, which is added frozen, fails to be exposed to high enough temperature to kill whatever pathogen you are worried about, and you get bacteria from the vegetables that are able to survive because the frozen sauce keeps them from being heated to a lethality temperature. Your system is not valid and if you hadn't gone through the validation process you would have potentially served a very dangerous meal. You determine that after some adjustments you need a tempering step for the sauce so it is added as a cooked liquid instead of froze cubes, you move the location of the



monitoring to the final combined product temperature and suddenly the process works, your system is now valid! So how did you figure it all out? Did you spend a lot of money on lab tests? No, you took your scientific support that says bacteria grows on vegetables and meat and you used the critical operating parameters identified in the scientific support you made sure that you took temperature tests throughout your entire process. That's how you found out that the sauce and vegetables were not getting heated enough. The point of this is to validate the best place to put the CCP, not spend a lot of extra money, or time.

Validation of procedures (Implementation of those critical parameters and how they are implemented in your establishment), verification activities, etc.: you need to validate your procedures. For example if you make a large diameter sausage and just take a surface temperature to verify your lethality temperature you probably can't support that procedure. How do you find out? Easy; you had your team take temperatures from the surface, middle, ends, etc. of the product. You find that in order to get the lowest temperature reading you have to take a temperature in the middle of the product, or maybe you are doing rotisserie chicken and you find that the coolest place in the bird is in the thigh along the bone. Until you test the procedure you just won't know. Don't forget to make sure your verification activities are going to be good enough to catch when your system is failing before you ship product. Do you do enough verification checks? Are you calibrating your equipment frequently enough to make sure they aren't out of tolerance, does your record review give you enough time to find out that the operator missed a check, or didn't realize that there was a deviation and still keep control of the product? While this can appear to be overwhelming when you are setting up your initial validation protocol you will find that it is just good management and business sense. Fixing a problem before it ruins your business is always good!

For example: You produce a specialty hot dog for a space program. Your hot dogs are exposed to a lethality of 189°F for ten seconds, (in your HACCP Plan as a CCP), have add lactate to the product, and then after its packaged you post pasteurize the product in package. (This is also in the HACCP Plan as a CCP). In your RTE program you are making an alternative 1 product because you have both an antimicrobial agent added to your product and you use a post exposed treatment for LM, and you use the USDA compliance guideline for your supporting document. When you design your initial validation protocol you are going to want to validate the critical parameters that you use to control the LM. Let's start with your lethality critical limit. You made the decision for your lethality temperature based on the high fat content of your hot dogs and the fact that you heard somewhere that space programs demand that it be cooked to at least 189°F for ten seconds. You can't find any support for this temperature in scientific documents, everything is lower. You did find a document from 1959 that NASA and the US Army wrote that references this temperature but it doesn't meet current standards for supporting your CCP. You also have the USDA Appendix A guidelines. How do you validate the temperature? Do you need to take a bunch of lab samples? No, you will use the supporting documents



that you do have that show that the critical limit that is acceptable is less than your CCP, document your thought process, ie people in space can't get to the doctor so you are following the NASA document, and then you validate that you are actually able to reach that temperature time combination (the critical parameters). You do this by testing your smoke house for cold spots based on the configurations you use to load it, you validate that your monitoring and verification frequencies are sufficient to catch any potential failures in your system, etc. You then look at how to validate your RTE program. Again, you are using a compliance guideline so you don't need to validate the guideline, merely that you meet those parameters. You are validating your post packaging lethality treatment, you have a scientific document that is peer reviewed and you follow it exactly, you again validate that you are in fact able to meet it exactly. You then validate that you use the lactate as outlined in the compliance guideline (and manufacturer's instructions). You haven't spent a lot of money on lab sampling and you didn't waste any time, you know your system is valid!

You need to make sure that you validate your entire program, that includes GMP's, Pre-Reqs, Preventive Controls, etc.

Working with ongoing validation:

Ongoing validation, this is NOT verification! Remember, you verify that you are following your plan, you validate that the plan prevents unsafe food from being produced. You will want to periodically test your system to make sure you don't end up with what the military calls "mission creep". Has your system subtly changed over time? The employees were much more focused when you first rolled out the program however now its old hat and are they cutting corners? Has equipment become more or less efficient? How do you know when any of this happens? You build in stress tests, we recommend every six months or so, and retest the system. We recommend that you include product sampling to these tests for indicator organisms. If something is drifting you want to catch it before it becomes an issue. How you do this really depends on how you have designed your system however a good example is how many grinders focus on this ongoing validation in February and April, before the E.coli season really starts going. It helps them get a good view of how their system is currently working and helps them head off any weaknesses that have developed that could result in positive product when the prevalence of E.coli is at its highest (summer months). Again, this isn't a verification activity and while it can support a reassessment it isn't designed to "be" the reassessment. Design your ongoing validation program to give you an early warning if something is drifting the wrong way. You can use the data you collect to support decisions when you do a reassessment, and if you do detect something wrong you are automatically going to go into reassessment mode.

The process is the substantially same in FSP! for initial validation and ongoing validation, the difference is the time spent. In ongoing validation you will only run the validation for a very short period of time, sometimes only a single day periodically throughout the year. A good example is testing product for LM, as ongoing validation you may submit a product sample quarterly in addition to your normal environmental samples. In the ongoing validation module you will select the plan and or step you wish to validate. You will enter the necessary information; at this point you sign and date it. This then



becomes an active plan. You don't fill out the summary or findings until after the validation is complete. You collect the data and review it, using our LM sample it might be as simple as looking at the laboratory testing results. If there are no problems you will go back into FSP! and update that validation step by opening the active validation program and then completing the summary and the findings portions. Attach the records you generated and then sign and date it again. The plan now lists in the completed column. If something didn't work out you enter that also and make the changes to your plans and processes and then revalidate the changes following the same procedures.

FDA Food CGMPs:

Now if you are a FDA regulated facility you need to go into the Food CGMP's. These are regulatory requirements and you have to meet them however depending on your process there may be some that just don't apply. We recommend that if something is applicable that you use the standard text. You should also add the referenced GMP/Pre-Req/SSOP/HACCP plan that applies to it. For example you have a GMP for employee hygiene, does it cover people that have an open lesion? Maybe not specifically however if you require people to be in good health and don't allow them to work if they have any transmittable disease in your employee hygiene GMP you have addressed the FCGMP. Another example might be that you have copies of your water testing from your municipal water supply on hand. You can attach scanned copies and you now demonstrate your support for the CGMP.

FCGMP's will print off in your decision document, they are an integral part of your plan. For establishments regulated by the USDA you are required to meet the same requirements however it is up to you to design them. While not required of USDA inspected establishments the FCGMP's can be good tools to make sure you haven't missed anything.

Animal Feed CGMPs:

If you are an animal feed establishment you have an additional set of requirements. There are four basic types of requirements for feed establishments. Pet Food, Warehousing and Distribution, Medicated and non-medicated feed, all are very similar to Food CGMPs and you will follow Food CGMPs in your production. In most cases you will have developed a program for another purpose that covers the requirements, for example training. Your training program (GMP) is there because you need to train employee's to be efficient however it also serves a food safety purpose, if the employees are properly trained they won't make mistakes causing food safety issues. We recommend printing the self-audit for the type of feed you are producing and use it as a template to design your programs, most will be Ancillary SSOP's.

Getting started with Allergen control:

Your Allergen control program identifies the allergens you use, the date that you received the letters of guarantee. You then, through a series of questions, put together some general requirements to control allergens; identify how you handle changes between allergen and non-allergen or different allergen



containing products. You will also be able to either link to your Allergen GMP or create a new one that addresses specific (both to USDA and FDA) regulated facilities. The end product is your allergen program. Specific cleaning and handling procedures will be captured as either GMPs, Ancillary SSOPs, and or Preventive Controls. You will link to these in the Allergen Module.

Getting started with RTE/LMcontrol:

We have designed the RTE/LM program using the USDA's compliance guidelines as well as utilizing FDA requirements. The format we decided to use was the USDA's as it is the more comprehensive, and hence meets the requirements of the FDA also. The basic gist of it is that you determine how you control LM in your products. (The Compliance Guideline is in the reference library) Do you use both an antimicrobial agent and a post lethality treatment? If so you are alternative 1. You will have addressed the adding of an antimicrobial agent in the HACCP Plan, SSOP, or a GMP. If you used a post lethality treatment you will have identified it in the HACCP Plan. Those documents will be your references. If you just add an antimicrobial agent or just a post lethality treatment you are alternative 2. Again, you will identify what program you use to control it however you will also answer some questions like how many packaging lines do you have, how many tests per line do you take, the frequency, etc. You will also answer questions concerning environmental testing, to include how many samples, locations, etc. You will have the ability to attach your test and hold procedures and also determine your product testing frequency as part of your ongoing validation. In the event you just use sanitation to control LM on your RTE product you go through a much more detailed set of screens to develop your program. We strongly encourage both FDA and USDA regulated facilities to read the documents in the support library under LM control. It is a lot of reading however the concepts such as rotating sanitizers can be of great assistance when putting together a solid LM/RTE program.

Getting started with Product Trace Back:

Product trace-back is a requirement for both USDA and FDA regulated facilities. FSP! comes with a preloaded program or you can develop your own. The key to trace-back is making a system that is simple and works. You need to know who you sold your products to and what they were made with, to include who you received them from. The forms that we have developed will assure that you have the information you need should you find yourself in a situation where you need to rapidly trace product either back to who sold it to you or product that your customers have received that you have to get back. When coupled with your recall program you will be able to minimize the amount of time you may have to spend, as well as limit the damage to your company by maintaining good records. We have included a section of the user manual that has more detailed information concerning Trace-Back later in this manual.



Getting started with Food Defense:

Food Defense is set up so that you can check specific pre-loaded blocks and or add your own information. It is very self-explanatory. The key to a good food defense plan is the same for all of your programs, make it simple, something that is easy to implement, and something that you actually do. The food defense plan also address information security, please remember that FSP! is part of your information security, don't give anything but read access to those that don't need it!

Getting started with Humane Handling:

Humane Handling: If you slaughter livestock the law is very clear, you must treat the animals that you slaughter humanely. Our humane handling module is based off the same regulatory checks used by the USDA. It is very straight forward. Humane handling of livestock isn't just the right thing to do because consumer groups want you to; it has a direct impact on the quality, and in some cases, the wholesomeness of the meat you produce. FSIS is under a lot of pressure to take actions and shutter plants that abuse animals, as you are aware the definition of abuse can be a moving target. Some of the areas that can be easily taken care of on your barn and receiving facilities, go through them with an eye to injury potential and the ease of movement of animals. What works for one species does not work for another. There is a lot of information available about designing your facility so we won't go into that; however, we have seen time and time again something as simple as changing the way a gate swings, or blocking an area from the animals view totally change the way animals move. The other thing to remember is that consumer groups hate shock-prods. If you have one in your facility you are often guilty of abuse even if the thing hasn't been used in ten years. We strongly recommend that your employees who handle live animals be carefully selected, a good employee can move just about any animal without touching them. Poorly trained employees or those that are rushing will get you in trouble. Your stunning system needs to work right every time. There is no excuse. Back up knocking mechanisms are necessary, they must work! Have a plan on how to deal with very large animals. When extremely large bulls show up you may want to switch to a shotgun. Sounds extreme however go through the lists of plants suspended and you will find pneumatic bolts, hand held captive bolt devices, 357 Mag pistols, 30-30 rifles, etc. have all failed to render large bulls unconscious. Again, we can't emphasize enough the role of having a properly trained team of employees play in the success of your humane handling system. No one wants to be named in as a violator! The final comments concerning designing your humane handling program are to make sure that you perform self-audits. We strongly recommend that you have both people familiar with your humane handling system and someone who knows nothing about your humane handling system perform the self-audit. This will give you a new set of eyes and a different perspective. The checklist for the self-audit in FSP! L1 unlike many other checklists it is not scored, it's a pass or fail. Fail any one area and the entire audit is a failure pending your corrective action. Remember the purpose of the checklist is to review your program with the intent to find ways to improve the program, without wasting a lot of time. If you wish to use a scored checklist please use Bing or Google search engines, there are a lot of them out there. One word of



caution concerning scored audits; they take a lot more time and in the end aren't as effective because if you "pass" you think you are ok. Most regulators use a pass/fail system. Either you pass or you fail. The self-audit is worthless if you "pass" it and then fail the regulatory audit!

Getting started with Poultry GCP:

Poultry GCP: While most poultry is vertically integrated, the rise in small poultry producers and the move to organic and free range poultry has had a dramatic impact on poultry handling. Poultry production while not legally required to be as stringent as livestock production does have the same basic rules. If you don't treat the birds correctly you fail to maximize your return on your investment. No matter if you are a farmer or a slaughter establishment; you must create your program so that you provide the maximum care for the live birds. In range birds controlling predation can be a major issue, injured birds easily become susceptible to disease that they then spread. How do you deal with them? How often do you check for injured birds? While the CGCPs are designed for the slaughter establishment they are totally applicable for all phases of raising poultry and bringing them to market. Any goose raising operation will tell you in large flocks there are always some birds that become "slows", they are much like swine, they will sit in place, given time they will become ambulatory and follow the rest of the birds. If you design your plan knowing the species you are dealing with you will be able to take these types of factors into account. Again, training is paramount. An employee that is properly trained knows how to move birds, handle them without injuring them, and can keep them calm. An untrained employee can cost you five times his or her salary due to product lost because of broken wings, joint damage, etc. The poultry good commercial practices incorporate your written program with a self-audit. As you go through the wizard you will be asked a series of questions, you select yes, or no and then make comments. The questions include recommend times or other industry standards. As you answer the questions the questions you are building your GCP's. After you have completed answering the questions your Poultry GCP's are ready to be implemented. The final comments concerning designing Poultry Current Good Commercial Practices handling program is to make sure that you perform self-audits. We strongly recommend that you have both people familiar with your program and someone who knows nothing about your program perform the self-audit. This will give you a new set of eyes and a different perspective. The purpose of your self-audit is to find ways to improve the program, without wasting a lot of time.

A note about medical residues and antibiotics. You will address both in your HACCP Plan or some other part of your program if you produce from the farm to the slaughter facility. The public and by extension the regulatory agencies are putting more emphasis on this area. It is not worth the trouble a positive gives you, if you have a sick animal and it has been treated don't bother going to slaughter with it! It will be tested at the slaughter plant and you will be getting a visit from the FDA. It's just not worth it! Producers, stockyards, etc. need to keep good records, you need to be in a position to prove you met the withdraw time if you are shipping animals that have been treated. We can't



emphasis this enough, the slaughter plants are being pushed very hard to stop purchasing animals from violators. Currently they are being advised to stop purchasing for repeat violators however government regulators are pushing to stop them from purchasing after a single positive!

Reassessing your Food Safety Program

Reassessment

What is reassessment? It is simply looking over your food safety programs and determining if you need to make a change.

When should I do a reassessment? You should reassess your food safety program whenever you make a change that impacts your process, this might be using a new or different piece of equipment, changing personnel, changing the formula or process that you use, or if you have a unforeseen hazard, or a deviation from a critical limit. Most regulatory requirements are for you to reassess yearly if there are no changes or events that trigger a reassessment

Reassessment at six months:

So you have built your SSOP, some GMP's, Pre-Requisite programs, HACCP Plan, etc. You have validated it, you are done right? Not quite; you need to give it a good go over and determine if you need to make any changes. After making major changes you typically will be validating for the first 90 days as we said earlier. We recommend that you perform another review complete review/reassessment at six months after implementation. The reason is that many employees will be comfortable with the program by then, you will find areas that you can change to make it more efficient, and areas where people are starting to cut corners. .

In FSP! its easy to do, open the HACCP Plan, archive the old plan, and make any modification or none depending on what you determine. You put the reason for the reassessment in the system so it tracks it for you.

Printing:

You will find in some sections you can print a blank form (Product trace back) or a program (Recall Management), you can also go to the printing menu and print your programs and blank forms.

Emailing or Sharing your documents:

When you create a document, be it a decision document, HACCP Plan, Hazard Analysis, etc you can open that document from the printing page, merely select the document you want and click print, it will open



up in Adobe PDF format. You can either print or save the file. For more information using PDF files please see: <http://helpx.adobe.com/acrobat.html> on the internet.

Product Trace-Back in depth:

Each firm or establishment must be able to follow (or trace) product both forward and backward in its supply chain.

What does this mean? Simply put you need to have records of everything you receive and be able to quickly and easily tie them into what you produce, and then track it to your customer, again quickly and easily.

This can be a huge paperwork burden however it is a legal requirement for both USDA and FDA regulated facilities.

There are numerous ways you can do this, if you use electronic records Food Safe Pro! can do this for you by utilizing its trace back module.

Often times you already are doing those things necessary for a trace back and often times establishments have these procedures in their GMP's. In Food Safe Pro! L1 and L2 you can link your trace back procedures directly from you GMP to the Trace back plan, or if you aren't you can use the trace back plan to put these programs in place.

If you rely on paper you have a larger challenge. For example if you purchase bulk Spices and other items such as meat trim to make sausage, bulk loads of casings, and you only make 15 pounds of sausage a week you may have issues figuring out what to recall if your spice mix is implicated in a recall and you don't have any records, or minimal records. Or maybe you get your meat trim from multiple suppliers and you used some of the lean in different sausage blends....then there is a recall by one of your suppliers. Do you know what was implicated? Another example is that you get in flour for your bakery items; it comes in bulk or pre-weight. Your bakery products are found to be contaminated with glass however you didn't have any glass in your facility, ie it came from a supplier. How do you know what supplier you used to make the bakery item? It all comes back to being able to quickly and accurately track your production, from your suppliers to your customers and vice versa.

A simple way of doing it is to create a record keeping system. You assign a lot number to everything that you receive, for example Flour-01012013a, Flour-01012013b, etc. on a receiving log (Figure 1) and then tag each product with that lot number. Each of these lots is then correlated to the actual supplier of the product. You can even use it as an inventory card and document what you used it in. This helps you if your supplier calls and says they have a problem with the product, it will help you to quickly figure out what products that you produced that may be contaminated, see figure 1 for an example.



You then maintain batch sheets of what you produce, again tracking ingredients that are used. See figure 2 for an example.

The next record you need is the shipping record. On it you capture what you shipped and to whom. See Figure 3 for an example.

The final record you need is a spillage/waste record. When something is thrown out you want to be able to show the regulator that your numbers match, or they are going to ask who you sold the “missing” product to. See Figure 4 for an example.

The key is being able to quickly reach into the file and pull out what you need. There are many ways to set a paper based system up. In most cases the finished product is the main folder and is organized by date. If you have a problem with a product you generally know what date you made it on. You can then pull it and cross reference your batch sheets, which in turn allows you to cross reference your receiving records. Food Safe Pro! L1 and L2 both come with forms to meet your needs and print for your use; you can either describe your trace back plan in the text area or upload a file if you already have one created. Once it is in Food Safe Pro! you don’t have to worry about losing the plan or the forms, they are always available in the program.

Maintaining paper records is extremely time consuming, that’s why we developed the Trace back module for Food Safe Pro L3. It automates your receiving, batching, and shipping logs all in one place, and it’s customized for your facility so that it works for you.

Figure 1 Receiving record:

Receiving Record Detail 3

Product: 1

Date: Qty:

Shipping Company: 2

Vehicle #:

Invoice / P.O #: UPC / SKU #:

Supplier: 1

Supplier Lot #:

Product Condition:

Product Temp:

Amount Rejected:

Rejection Reason:

Assigned Receiving Lot#: Assign Next Lot#

Items Received:

Date	Lot #
5/18/2013	518131

Cancel Save Receiving Record



Figure 2, batching record:

Batching Record Detail 3

Final Product : Bread 1LBS Wholesale Qty {lbs} Produced : 225
Product Lot # : 5062013 Qty {final packages} Produced : 225
Production Date / Time : 00 / 00 / 0000 Production Operator : Drew
UPC / SKU # : 0194613257 Packaging Operator : Supervisor 1

Ingredients Used In Batch

+	Ingredient Name	Amount Used	Lot #
-	Flour, bulk	200	5062013

Figure 3 Shipping Record:

Shipping Record Detail 2

Customer : We like Bread 1 Date : 5/18/2013
Contact Person : Mr. Donovan
Phone # : 1111111111
Email Address : donovanM@werlikebread.com
P.O. / Invoice # : 0

Billing Address : 1111 Bread way

Shipping Address : 1111 Bread way

Items Shipped

Shipping Item Name : bread, 1 LBS 0
Qty : 225
Lot# : 5062013

Cancel Save Shipping Item



Figure 4 Inedible record:

Inedible Record Detail 2

Date : 05 / 18 / 2013

Lot # : 518131

Product # : Flour, Bulk 0

Qty : 775

Reason : Roof Collapse, soaked the flour

Disposal Method : Moved into normal inedible, denatured W/Ink

Cancel Save Inedible Item

Here is the FSP! Recommended Trace Back Program, you can easily copy and paste this into your Trace-Back GMP from the Trace-Back module:

FSP! L1 Recommended Trace Back Program:

1. Receiving
2. Batching
3. Shipping
4. Spillage/Waste
5. Operations

1.Recieving

When we receive products, be they spices, raw ingredients like flour our primal cuts of meat, packaging material, chemicals, etc. we capture the basic information about that product and assign it a unique code.

Codes are assigned as follows: Product name, the date it is received (Month/Day/Year), sequential letter and number. For example 3 shipments of flour received on May 1, 2012 would be identified like this: Flour-Bulk 05012012A1, Flour-Bulk 05012012A2, and Flour-Bulk05012012A3. Codes are attached to the product and its placard used to identify its storage location.



Information that is collected during receiving is recorded on the receiving form. The receiving form is used as the product placard, as the product is used the placard is updated to show what products that it was used in.

2. Batching

When we make product we capture basic information on the batching record and assign it a lot number. Lot numbers are assigned as follows: Product name, the date (Month/Day/year/time) it was made (Final packaging date/time for multi day production), and a sequential letter and number. For example for three lots of bread made on May 10, 2012 the lot number reads: 1# White Bread 051020121032A1, 1# White Bread 0510201211241A2, and 1# White Bread 051020121334A3. The first lot finished packing at 10:31AM, the second lot finished packaging at 12:41PM, and the third lot finished packing at 1:34PM.

3. Shipping

When we ship product we capture basic information on the shipping record that includes the lot number, who it was shipped to, etc.

4. Spillage/waste

Anytime product is lost we record the amount on our inedible/spillage/waste record to include the lot number we have assigned to it.

5. Operations

When product is received we write our receiving code on each case of product and then attach the receiving record to the placard location in storage. As the product is used in production the batch lots and amount used are recorded on it. In the event that the sheet is full and there is still product we attach an additional sheet to the original sheet. When the product has been used up, the sheet is turned into the office and the amounts are cross referenced with batching sheets and the spillage report to verify that all product is accounted for. The receiving record is then filed in the receiving file under our suppliers name by receipt date.

When batch sheets are completed they are filed in the pending file along. As the lot is shipped the shipping date of the lot and quantity are documented on the back of the batching record for each shipment until inventory is exhausted. When inventory is exhausted and the batch sheets have been reconciled with the receiving sheet, they are filed by production date. The shipping records are filed by shipping date. Spillage is filed in the spillage file by date.

In the event that our suppliers notify us of a problem we will pull the applicable product receiving sheet and use it to pull the batch sheets, shipping sheets, and spillage sheet and provide them to the Recall team.



DKM Integrated Software Solutions LLC
2015 Wilson Street, DSDS, Menomonie, WI 54751

If we are notified of a problem with product that is in commerce we will pull the applicable batching sheet and use it to identify our shipping records, and then provide the packet to the Recall team.

Signed by:_____. Date:_____.
Title:_____.

Step by Step instructions:

These instructions correspond to the fields you will go through is FSP! When you left click on the “?” button next to the field these help sections are displayed. For more detailed help please right click on the “?” button or see the “designing your food safety program” section. This section is provided for your information, everything in this section is available via pop-up menus in FSP! L1

Registration:

1. Serial number field: Enter serial number, note: you can click the tab button on your keyboard or use your mouse to move to the next field.
2. Company Name Field: Enter Company name
3. Doing Business as Field: Enter your primary Doing Business as.
4. Address Field: Enter your address
5. City, State, and Zip Field: Enter your city, state, and zip
6. Phone Field: Enter the business primary phone number
7. Email Address Field: Enter the business primary email address
8. Administrator Name Field: Enter the person’s name who is going to be the primary administrator for Food Safe Pro.
9. Password Field: Create a strong password. See the user manual for help creating a strong password.
10. Password Field 2: Renter your password and **click tab**.
11. Facility Field: Select the type of facility that best describes your company, you may select more than one, Click continue
12. Primary Regulator Field: Select who the primary regulator is. If you are not sure select Dual Jurisdiction. Click continue
13. System Users Field: Using the + key add authorized users for Food Safe Pro! If you make a mistake or wish to delete someone highlight their name and click the “-” arrow. We strongly



recommend that you add “designated Employee”, this will allow you more flexibility in FSP! L1.

14. User Detail Pop up Field: System User Detail Pop up (Please note that you can add and modify later in the administrative screens):
15. Employee Name Field: Enter the user name of the employee.
16. Employee Password Field: Enter a strong password for the employee-see the user manual section on security.
17. You will skip the location field, this is only available in the L3 and L4 modules.
18. In access level you will select the level of authority you wish the user to have.
19. Company Phone Number Field: Enter their phone number in the establishment.
20. Employee phone number Field: Enter a mobile number if they have one.
21. Employee Email Address Field: Enter their email address if they have one. Click save and repeat as necessary to add all of your authorized users.
22. Logo Field: Click the upload logo and navigate to your computer to where your logo is. Logo's work best when they are rectangles however using a picture editor you can modify and reload as necessary later in the administrative screens.
23. Click Save

SSOP:

24. At this point you are in the main screen for FSP!, We suggest that you start with your SSOP.
25. Click SSOP in the left screen.
26. Person with overall responsibility field: Select the person with overall responsibility in the establishment for sanitation. If you have not entered them see “system Administration step 496” of this document for instructions on how to enter them.
27. Establishment Schematic Field: Next click Browse under the Establishment Schematic and navigate to where you have your establishment schematic stored on your computer. This step may be bypassed.
28. Lock-out/ Tag Out Program Field: Next click Browse next to the “Lock-out/Tag out Program and navigate to your lock out/tag out program, this step may be bypassed.
29. SSOP Pre-Op Monitor Filed: Next select the person who will be the SSOP Pre-Op Monitor for very small plants or the SSOP monitor Supervisor for larger establishments.
30. SSOP Operational Monitor Field: Next select the person who will be the SSOP Operational Monitor for very small plants or the SSOP monitor Supervisor for larger establishments.
31. General Sanitation Discussion Field: Next fill in the General Sanitation Discussion field. In this field you will enter basic information concerning sanitation such as your company's general policy, if you use an outside cleaning company, your sanitation philosophy, etc.
32. Next click “save plan data”.



33. Pre-Operational Sanitation Field: Next click on the “pre-operational sanitation tab” that is at the top of the screen. Please note that the dictionary that comes with FSP is basic, as you go through you can add words that it does not recognize and it will remember them.
34. Floors Field: You will add the procedures you use to clean and sanitize Floors in the procedures fields, the frequency that the procedures are performed in the frequency field, your monitoring procedure (to include frequency of monitoring) in the monitoring procedures field, and then attach blank records by clicking the “+” button in the records field. When you press the “+” button navigate to where you have the blank form stored on your computer, click open and it is attached. Then Click save and next.
35. You will repeat the instructions in block 28 for: walls Ceilings, stationary equipment, mobile equipment, and personal equipment. When you have finished entering them all click save.
36. Operational Sanitation Field: Next select the Operational Sanitation Tab.
37. Operational Sanitation opens with Product Hygiene. The basic instructions are the same as in block 28, You will add the procedures you use to maintain Product Hygiene during operations in the procedures fields, the frequency that the procedures are performed in the frequency field, your monitoring procedure (to include frequency of monitoring) in the monitoring procedures field, and then attach blank records by clicking the “+” button in the records field. When you press the “+” button navigate to where you have the blank form stored on your computer, click open and it is attached. Then Click save and next.
38. You will repeat the instructions in block 31 for: Operational Hygiene, non-meat ingredient hygiene, and packaging material. When you have finished entering them all click save and close.
39. Designees Field: Next click the Designee’s tab. You will then click the “+” button to add sanitation monitors, and other employees that you want to identify with having sanitation responsibilities.
40. If you wish to remove an employee select them from the list and click the “-” button.

Food Safety Plans:

GMPs:

41. GMP’s Field: Next click on GMP’s/Prerequisites/Preventive Controls/Add SSOP link on the left navigation screen.
42. Add GMP Field: Click the “Add New GMP Button”.
43. GMP Name Field: Put the title of the program into the GMP Name field.
44. GMP Procedure Field: Put the procedure that is followed in the GMP Procedure field.



45. GMP Monitoring Field: Put the monitoring procedure for the GMP in the GMP Monitoring field.
46. GMP Monitoring Logs Field: Use the "+" button to add blank records used with the GMP. If you wish to remove a record highlight it and select the "-" arrow.
47. GMP Supporting Documents Field: Use the "+" button to add supporting documents that are used to support the GMP. If you wish to remove a record highlight it and select the "-" arrow.
48. Signature Field: The person with overall authority then selects their name from the drop down and clicks the signed button. The date automatically appears and the GMP is active.
49. Repeat as necessary to add all of your GMP's.

Prerequisite Programs:

50. Click the "Add New Prerequisite Program Button".
51. Put the title of the program into the Prerequisite Program Name field.
52. Program Procedure Field: Put the procedure that is followed in the Prerequisite Program Procedure field.
53. Program Monitoring Field: Put the monitoring procedure for the Prerequisite Program in the Prerequisite Program Monitoring field.
54. Monitoring Logs Field: Use the "+" button to add blank records used with the Prerequisite Program. If you wish to remove a record highlight it and select the "-" arrow.
55. Supporting Documents Field: Use the "+" button to add supporting documents that are used to support the Prerequisite Program. If you wish to remove a record highlight it and select the "-" arrow.
56. Signature Field: The person with overall authority then selects their name from the drop down and clicks the signed button. The date automatically appears and the Prerequisite Program is active.
57. Repeat as necessary to add all of your Prerequisite Program's.

Preventive Controls:

58. Click the "Add New Preventive Control Button".
59. Name Field: Put the title of the program into the Preventive Control Name field.
60. Preventive Control Procedure Field: Put the procedure that is followed in the Preventive Control Procedure field.
61. Program Monitoring Field: Put the monitoring procedure for the Preventive Control in the Prerequisite Program Monitoring field.
62. Monitoring Logs Field: Use the "+" button to add blank records used with the Preventive Control. If you wish to remove a record highlight it and select the "-" arrow.



63. Supporting Documents Field: Use the “+” button to add supporting documents that are used to support the Preventive Control. If you wish to remove a record highlight it and select the “-“arrow.
64. Signature Field: The person with overall authority then selects their name from the drop down and clicks the signed button. The date automatically appears and the Preventive Control is active.
65. Repeat as necessary to add all of your Preventive Controls.

Add a Ancillary SSOP:

66. Click the “Add New Ancillary SSOP Button”.
67. SSOP Name Field: Put the title of the program into the SSOP Name field.
68. SSOP Procedure Field: Put the procedure that is followed in the SSOP Procedure field.
69. Prerequisite Program Monitoring Filed: Put the monitoring procedure for the SSOP in the Prerequisite Program Monitoring field.
70. Monitoring Logs Field: Use the “+” button to add blank records used with the SSOP. If you wish to remove a record highlight it and select the “-“arrow.
71. Supporting Documents Field: Use the “+” button to add supporting documents that are used to support SSOP. If you wish to remove a record highlight it and select the “-“arrow.
72. Signature Field: The person with overall authority then selects their name from the drop down and clicks the signed button. The date automatically appears and the SSOP is active.
73. Repeat as necessary to add all of your unique SSOPs.

HACCP:

74. List Active Plans Field: In the left hand menu select “List Active Plans” under HACCP.
75. New Plan Field: Click “New Plan”
76. Plan Label Field: Name the plan in the plan label field.
77. Effective Date field: Put the effective date in the effective date field. It will default to today’s date.
78. Reason Modified/reassessed Field: Explain why the plan was modified/reassessed.
79. Products Covered Under This Plan Field: To add products covered under this plan click the “+” button. To remove a product highlight it and click the “-“button.
80. New Products Pop Up Screen.
81. Products Field: Enter the name and type of product in the products field, for example Raw not Ground-Beef Steaks, or Produce-watermelon. Individual products such as T-Bone, ½ inch are entered in Trace-Back module for versions L3 and L4



82. Type of Package Field: List all types of packaging used in the type of package field.
83. Expected Shelf Life Field: List the expected shelf life at both refrigerated and frozen state if they are both applicable or in the case of produce or alfalfa at "normal storage" temperatures.
84. Label Approval Field: If you have approved labels from the USDA click yes, otherwise select no for label approval.
85. Distribution Controls Field: If special distribution controls are needed list them here. Generally you will state keep refrigerated or frozen as applicable and protect from contamination with filth.
86. Intended use: this field prepopulates with "retail & Wholesale", change if you have a different intended use.
87. Expected Customer: this field prepopulates with General Public, if your customers are a high risk population identify them here.
88. Click save, repeat as needed to enter all products covered under this HACCP Plan.
89. Process Steps Covered Field: To add process steps click the "+" key.
90. Step Label Field: In the step label enter the step, for example Prepare ground for planting or receive raw meat.
91. Step Description Field: Step Description. Add a detailed description about the process step, include relevant facts concerning the location, or event. Include the overview of the documentation you reviewed to determine if there are hazards associated or not.
92. Chemical, Physical, biological, or Radiological. You will select no if there is no hazard identified, the system will automatically enter "None Identified" in the block. If you have identified a hazard select "yes" and a pop up window will appear that will take you through a series of screens.
93. Selecting yes to a hazard. Screen title is "Hazard Type:" and the type of hazard.
94. Hazard Identified Field: In hazard identified put the specific hazard you have identified.
95. Reason for Decision Field: In the Reason for the decision describe in detail why you consider this a hazard.
96. Controls in Place Field: In controls in place list all the controls you have in place. You may determine you have a hazard but due to several different controls it isn't likely to occur, this may be a preventive control.
97. In the "Hazard Likely to Occur" block select yes or no and then in the text area describe your reason for making the decision. Be specific and detailed.
98. In the document library (Attach supporting documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to



identify the hazard, determine controls, and to determine if the hazard is likely to occur, then click save.

99. You will then answer if this is a critical control point or not. If no check no, and then click save process step. Repeat adding process steps. If you finish adding all process steps and there aren't any critical control points identified go to step"153"; however if you identify a critical control point and check yes. You will be taken to another screen.
100. Description of Critical Control Point: Put a description of the Critical operation, values, etc. related to the critical control point.
101. Attach Blank CCP Documents: Attach any blank forms you use to monitor the CCP.
102. Critical Limit: Put the specific critical limits that apply to the CCP here.
103. Justification of Critical Limit: Give a detailed justification of the critical limits.
104. Location of Critical Control Point Monitoring: Give the specific location of the critical control point.
105. In the document library (Attach supporting documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to identify the critical limit.
106. Justification of Monitoring Location: Give a detailed justification of why this location is the best to monitor the CCP.
107. In the document library (Attach supporting documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to identify the location of the CCP monitoring.
108. Click Continue.
109. In the monitoring Procedure field enter a detailed description of how you monitor the critical control point.
110. In the justification for Monitoring Procedure field justify why this procedure is adequate at assuring the process is under control.
111. In the document library (Attach supporting documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to support the monitoring procedure and the frequency of monitoring.
112. In the "Who Performs the Monitoring Procedure" field select the person who actually performs the monitoring function. We suggest you have a "Designated Employee" set up for L1 who is selected. See System Administration (Step 448) to set up an employee.
113. Frequency Monitoring Field: Enter the frequency that you monitor in the frequency of monitoring field.



114. Justification of Frequency Field: Give a detailed justification why the frequency of monitoring is sufficient to assure your system is in control in the Justification of Frequency field.
- 115. Next click the “Verification Tasks” button.**
116. You will be at the “Direct Observation” verification function.
117. Person who performs the Function Field: Select the person who performs the verification task.
118. Frequency Field: Select the frequency of the verification Task.
119. Monitoring Procedure Field: Give a detailed description of the monitoring procedure used for the verification task.
120. Records Field: Attach blank records used to perform the verification task.
121. In the document library (Attach supporting documents) click on the library icon, click “+” button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to identify the critical limit.
122. Click “Save Process Step” button.
123. Calibration of Equipment Field: You will be at the “Calibration of Equipment” verification function.
124. Person Who Performs this Function Field: Select the person who performs the verification task.
125. Frequency Field: Select the frequency of the verification Task.
126. Monitoring Procedure Field: Give a detailed description of the monitoring procedure used for the verification task.
127. Records Field: Attach blank records used to perform the verification task.
128. In the document library (Attach supporting documents) click on the library icon, click “+” button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to identify the critical limit.
129. Click “Save Process Step” Button.
130. You will be at the “Records Review” verification function.
131. Person Who Performs this Function Field: Select the person who performs the verification task.
132. Frequency Field: Select the frequency of the verification Task.
133. Monitoring Procedure field: Give a detailed description of the monitoring procedure used for the verification task.
134. Records Field: Attach blank records used to perform the verification task.
135. In the document library (Attach supporting documents) click on the library icon, click “+” button and navigate to the place on your computer where you have stored the file, highlight



the file and click open. Repeat until you have added all of the supporting documents used to identify the critical limit.

136. Click "Save Process Step Button.
137. You will be at the "Corrective Actions" verification function.
138. Person Who Performs this Function Field: Select the person who performs the verification task.
139. Frequency Field: Select the frequency of the verification Task.
140. Monitoring Procedure: Give a detailed description of the monitoring procedure used for the verification task.
141. Records Field: Attach blank records used to perform the verification task.
142. In the document library (Attach supporting documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents used to identify the critical limit.
143. Click "Save Process Step" Button.
144. You are now at the corrective actions screen. You may enter your own corrective actions however FSP! recommends that you accept the pre-printed text. To do so click the >> arrows for the four steps in corrective action. You can modify the text after it has moved into the text field.
145. Designated Employee Field: Select the employee who performs corrective actions functions (FSP! recommends you select "Designated Employee" for L1 versions).
146. Use the "+" to add blank records used as part of corrective actions. To do so click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the Documents you use.
147. Click Save and next.
148. You are now in the unforeseen hazard screen. You may enter your own actions to take in response to an unforeseen hazard however, FSP! recommends that you accept the pre-printed text. To do so click the >> arrows for the four steps you will take if you have an unforeseen hazard. You can modify the text after it has moved into the text field.
149. Designated Employee Field: Select the employee who performs the actions you take in the event of an unforeseen hazard (FSP! recommends you select "Designated Employee" for L1 versions).
150. Use the "+" to add blank records used as part of an unforeseen hazard. To do so click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the Documents you use.
151. Click Save and close.
152. Repeat until all hazards that have been identified are complete (From step 93 to 152).



153. After all hazards have been identified as either yes or no for chemical, physical, Biological, or in the case of FDA regulated/Dual Jurisdiction regulated facilities Radiological click save process step.
154. Continue adding process steps until all process steps are complete. If you have to take a break click the save button to save your work.
155. Prepared By Field: After all process steps have been added and you are ready to turn the HACCP Plan "on" or "make it active" enter the person's name who prepared the document.
156. Sign Field: Then click the "Sign" Button.
157. The person who is signing must be the person logged into FSP! to sign and meet the requirements of Title 11. If Title 11 doesn't apply to your facility and you intend to print and sign the printed copy use the person logged on to FSP! for the signature
158. Click Sign.
159. Now click the "Save" button. The plan is now active!

FDA Food CGMPs:

160. FDA Food CGMP's Field: Now click "FDA Food CGMP's" on the left side navigation menu.
161. USE Standard FDA Regulation Field: FDA CGMP's are regulatory requirements as such if you are regulated you must follow them. To make it easier to incorporate them into your food safety plan you can use the "down arrow to accept the text from the regulation. The text can be modified to meet your specific needs.
162. Reference Field: In the reference section use the drop down arrow to select any other programs you have that address this requirement.
163. FDA CGMP Supporting Documents Field: In the Supporting document section use the "+" arrow to open the selection window, navigate to where the supporting document is kept, highlight it, and click open. Repeat until you have attached all documents that support this part of your CGMP.
164. Click "Save & Next".
165. Repeat step 161 through 164 until you get to the self-audit & Approval section.
166. In the Frequency field for self-audit enter the frequency that you perform them.
167. Who performs the self-Audit Field: Use the down arrow to select the person responsible for the self-audit
168. Click the "Upload Self Audit" if you have one that you use otherwise you can use the one that comes with FSP!, it can be printed in the print menu or by using the button at the bottom of this page.
169. Reference GMP-Pre Req/SSOP/HACCP/Plan Field: In the reference section select the program you use for conducting self-audits if you have one.



170. In the FDA –CGMP Supporting documents field select the documents that support your CGMP's if not already selected earlier in your program. You can also select the appropriate regulations from the resource folder that loads with FSP!
171. Prepared By Field: Select the person who has prepared the plan.
172. Signed By Field: Select the person who is signing the plan, please note that the person who is signing the plan must be logged into FSP! in order to sign it. Click in the check box under "signed" and the date will populate.
173. Click save and close. Your FDA CGMP's are done!

Animal Feed/Feed Plant GMPs:

174. Click the "GMP's Feed Plant" button on the left hand navigation screen.
175. Click the "Enter new GMP Button".
176. GMP Name Field: At the top of the pop up window name the GMP. (Animal Feed is suggested)
177. Change the effective Date to the date you wish.
178. The created on date will self-populate.
179. Created by field: Enter your name.
180. Enter your GMP Statement. This is a general operating statement that you will use to identify key areas of your operation, it should be two to three lines and is intended as a summary, for example: Salmonella is our key concern in the production of our feed products, please see our HACCP Plan for specific controls.
181. Click Save and next.
182. In training put down how often you review or audit your program, of often your review or audit personnel and then supervision. You can add additional comments to the right in the remarks area. You will put in the date of the last audit and the program area that covers the audit, such as a Self-Audit GMP, prerequisite program, etc. Specific Requirements are found in the resource folder that came with FSP! and can be printed from the printing module.
183. Click Save & Next, you will go through all of the screens for animal feed, if they do not apply you can skip them until you come back to the main screen that has the GMP Name, effective date, etc. fields.
184. Click the "sign" button. Select the person with the authority to sign the document.
185. Next click the "Exit Animal Feed CGMPs" button to close the Feed GMP.



Allergen Control:

186. Next click the Allergen Control Program in the main left navigation screen.
187. Prepared By Field: Enter the person who prepared the program.
188. Effective Date Field: Enter the effective date.
189. Reason Modified / Reassessed: Enter the reason the program was modified or reassessed.
190. Select the allergens that you use in your facility, then select the date you received label approval (USDA regulated), then enter the date you received the letter of guarantee from your supplier that the allergen component was made utilizing a food safety program/that the product is safe for intended use.
191. Click "Save & Next".
192. If you don't have a letter of guarantee request form you can generate one by clicking the button.
193. You can also generate a request for third party audit findings.
194. Answer the three questions, yes, no or not applicable. We recommend that you have a customer complaint GMP that includes reviewing complaints for potential allergen issues, and that you also have a receiving GMP that includes reviewing labels to verify that the allergens coming into your establishment haven't changed without your knowledge. During your pre-shipment review process we recommend that review for potential issues with allergens specifically so that you don't inadvertently ship product with allergens.
195. How changes in production handled between allergen formulation and other production field are: Give a detailed description of what sanitation and other measures you implement to preclude cross contamination. Please remember to address airborne contaminants.
196. Letters of guarantee on file field: Check the appropriate box if you have packaging letters of guarantee on file.
197. "+" button, it will open a pop up window.
198. Packaging Material Field: Add the Packaging material.
199. Supplier Field: Add the supplier.
200. Date of Letter Field: Add the date of their letter of guarantee.
201. Remarks Field: Add any remarks.
202. Click Save and Next.
203. On this page select the appropriate program area that applies to the question. If you don't have a GMP you can create one by clicking the "create GMP" button.
204. Click Save.
205. Next go to the Allergen Control Program in the left screen menu and click the sign button.
Sign Field: Select the person with authority to sign the program.
206. Click the exit allergen control button.



RTE/LM Program:

207. Next Click the RTE/LM Program button on the left Navigation page.
208. Prepared By Field: Select the person who prepared the program.
209. Effective Date Field: Enter the date the program is going to be effective.
210. Reason Modified/ Reassessed: Enter the reason that the program is being modified or reassessed.
211. What Alternatives Field: Select what alternative you use in your facility. (See compliance guide for help)
212. For Alternative 1, check the alternative one box.
213. Alternative 1 Products Field: Click the "+" button to add the specific product produced that is covered under Alternative one. You can also add the product SKU.
214. Click save.
215. Repeat until you have added all the products that are covered by alternative 1.
216. Click "Save & Next".
217. What Post Lethality Treatment do you use? Field: Select the post lethality treatment you use.
218. Where is it identified in your HACCP plan? Field: Select the appropriate process step in your HACCP System that covers the post lethality treatment.
219. What anti-microbial agent do you use? Field: Enter the Anti-microbial agent that you use.
220. Where is it identified in? Field: Select the program that covers the anti-microbial agent.
221. Click save and next.
222. Annual Production Volume Field: Enter your annual production volume.
223. Date Last Reported to USDA Field: If you are regulated by the USDA enter the date you last reported your volume, the set reminder will not work in L1.
224. Do you test for? Field: Select what you test your product for
225. Product Testing Frequency Field: Enter your product testing frequency.
226. Conditions to implement, test, and hold field: Enter the conditions that result in test and hold.
227. Attach a Test and hold document field: Attach the document that supports your test and hold procedures, for example the compliance guide.
228. Testing methodologies the laboratories use field: Enter the testing methodology that your laboratory uses to test your product.
229. Attach a lab methodology document field: Attach a copy of the lab kit insert or other supporting document.
230. The Sample Collection procedure field: Describe the sample collection procedure.
231. Collection procedure document field: Attach support for your sample collection procedure.



232. Attach an additional testing document field? Attach any other supporting documents.
233. Other Validation Used Field: Describe any other Validation that you use.
234. Click Save and Next.
235. What alternatives you use field: For Alternative 2, check the alternative 2 box.
236. Alternative 2 Products Field: Click the "+" button to add the specific product produced that is covered under Alternative 2. You can also add the product SKU.
237. Click save.
238. Repeat until you have added all the products that are covered by alternative 2.
239. Click "Save & Next".
240. Select the appropriate category requirement, either post lethality treatment or antimicrobial agent.
241. What post lethality treatment do you use? Field: If you use a post lethality treatment select the post lethality treatment you use.
242. Where is it identified in your HACCP plan? Field: Select the appropriate process step in your HACCP System that covers the post lethality treatment.
243. What antimicrobial agent do you use? Field: If you use an antimicrobial agent enter the Anti-microbial agent that you use.
244. Where it is identified field: Select the program that covers the anti-microbial agent.
245. Click save and next.
246. Enter your annual production volume.
247. If you are regulated by the USDA enter the date you last reported your volume, the set reminder will not work in L1.
248. Select what you test your product for (Add "Product" after the for)
249. Enter your product testing frequency.
250. Enter the conditions that result in test and hold.
251. Attach the document that supports your test and hold procedures, for example the compliance guide.
252. Enter the testing methodology that your laboratory uses to test your product.
253. Attach a copy of the lab kit insert or other supporting document.
254. Describe the sample collection procedure.
255. Attach support for your sample collection procedure.
256. Attach any other supporting documents.
257. Describe any other Validation that you use.
258. Click Save and Next.
259. What Alternatives do you use? Field: For Alternative 3, check the alternative 3 box.
260. Alternative 3 Products Field: Click the "+" button to add the specific product produced that is covered under Alternative 3. You can also add the product SKU.



261. Click save.
262. Repeat until you have added all the products that are covered by alternative 3.
263. Click "Save & Next".
264. How many packaging lines do you have? Field: Enter how many packaging lines you have.
265. Test per Line Field: Enter how many Food contact Tests you take per line per testing period.
266. Why is the Testing Frequency Sufficient? Field: Enter the testing frequency. (Monthly as an example)
267. Enter your justification as to why this frequency is sufficient.
268. Program Used Field: Select the program that you use to control your testing program.
269. Do you test for? Field: Check the appropriate organism or add what it is that you check for in other by checking the box.
270. Where are the locations you test? Field: Enter the locations that you test.
271. What is the size of the test site? Field: Enter the size of the test site, typically 12 square inches or the entire surface if it is smaller.
272. Conditions to implement test and hold field: Enter the conditions that result in test and hold.
273. Attach a test and hold document field: Attach the document that supports your test and hold procedures, for example the compliance guide.
274. What testing methodologies do the laboratories use? Field: Enter the testing methodology that your laboratory uses to test your product.
275. Attach a lab methodology document field: Attach a copy of the lab kit insert or other supporting document.
276. What is the sample collection procedure field: Describe the sample collection procedure.
277. Attach a collection procedure document field: Attach support for your sample collection procedure.
278. Attach an additional testing document field: Attach any other supporting documents.
279. Describe any other Validation that you use.
280. Click Save and Next.
281. Do you test for field: For environmental sampling select the organism that you test for.
282. Where are the locations you test? Field: Enter the locations that you perform environmental sampling (non-food contact/non-product testing).
283. Justification for these site locations field: Justify why you have selected these sites.
284. What is the size of the test site? Field: Enter the size of the test site, typically 12 square inches or the entire surface if it is smaller.
285. Justification for size of test site field: Justify the size of the test site.
286. Do you produce Hot Dog / Deli Products? Field: Check yes or no as applicable if you produce Deli or hot dog products.
287. Conditions to implement test and hold field: Enter the conditions that result in test and hold.



288. Attach a test and hold document field: Attach the document that supports your test and hold procedures, for example the compliance guide.
289. What testing methodologies do the laboratories use? Field: Enter the testing methodology that your laboratory uses to test your product.
290. Attach a lab methodology document field: Attach a copy of the lab kit insert or other supporting document.
291. What is the sample collection procedure? Field: Describe the sample collection procedure.
292. Attach a collection procedure document field: Attach support for your sample collection procedure.
293. Attach an additional testing document field: Attach any other supporting documents.
294. Describe any other Validation that you use.
295. Click Save and Next.
296. Special controls for Hot Dog / Deli Products Field: You may change or keep the text for Special controls for Hot Dog / Deli Products.
297. Click Save & Next.
298. What is your annual production volume? Field: Enter your annual production volume.
299. Date last reported to USDA Field: If you are regulated by the USDA enter the date you last reported your volume, the set reminder will not work in L1.
300. Do You Test For Field: Select what you test your product for
301. Product Testing Frequency Field: Enter your product testing frequency.
302. Conditions to implement test and hold field: Enter the conditions that result in test and hold.
303. Attach a test and hold document field: Attach the document that supports your test and hold procedures, for example the compliance guide.
304. What testing methodologies do the laboratories use? Field: Enter the testing methodology that your laboratory uses to test your product.
305. Attach a lab methodology document field: Attach a copy of the lab kit insert or other supporting document.
306. What is the sample collection procedure? Field: Describe the sample collection procedure.
307. Attach a collection procedure document field: Attach support for your sample collection procedure.
308. Attach an additional testing document field: Attach any other supporting documents.
309. Describe any other Validation that you use.
310. Click Save and Next.
311. Sign field: Click the "sign" button.
312. Select the person with the authority to sign the document. Please note that they have to be signed in to FSP! in order to sign.



Food Defense:

- 313. Next click on the Food Defense button on the main left side navigation screen.
- 314. Physical Security Field: For the food defense check the statements that apply to your facility and add any additional measures you take for the area covered in the "other text field". You will start with Physical Security.
- 315. Click Save & Next.
- 316. Repeat until you get to the information security section.
- 317. Who is the Information system administrator? Field: Enter the person who administers your computer system.
- 318. What virus protection do we use? Field: Put in the type of virus protection that you use. If you are using windows basic setup you will list "windows Defender".
- 319. What Anti-Spyware/Malware do we use? Field: Enter the type of anti-spyware/malware that you use. If you are using windows basic setup you will list "windows Defender".
- 320. What firewall system do we use? Field: Enter the firewall you use. If you are using windows basic setup you will list "windows Firewall".
- 321. How often do we require password changes? Field: How often do you require people to change their passwords?
- 322. Check the applicable check boxes for the remainder of this section and continue with the food defense module until you come to the Review section.
- 323. Additional Information for our Food Defense Plan Field: Enter any additional Food Defense information in the text field.
- 324. When you review the plan fill out the "Food Defense Reviewed section. Check Yes, enter the date, and select who performed the review.
- 325. Prepared By Field: Enter the person who prepared the Food Defense Plan.
- 326. Signed By Field: The person who has authority is to sign the plan, please note they must be logged in.
- 327. Click on Save and Close.

Humane Handling:

- 328. Next click on Humane Handling.
- 329. Date Prepared Field: Enter the date prepared.
- 330. Prepared By Field: Select the person who prepared the program.
- 331. Effective Date Field: Enter the date that the program is effective.



- 332. Reason Modified / Reassessed Field: Enter the reason you have modified or reassessed the plan.
- 333. Initial Review of Humane Handling Practices Field: Conduct the initial review of the Humane Handling practices you use.
- 334. Select Yes or No for each question and make any applicable remarks. Remarks should either clarify how you do something or make a recommendation for improvement.
- 335. Click Save and next.
- 336. Continue to answer the initial review questions.
- 337. General Provisions of our Humane Handling Program Field: In the general provisions section enter any information that is in a general nature about your program.
- 338. Click Save and Next. Prior to starting on this screen review the findings of your initial review and make any changes.
- 339. Who has oversight of our Humane Handling program Field: Enter who has oversight of the Humane Handling program.
- 340. How often do we review our Humane Handling Program? Field: Enter the frequency of reviews of the humane handling program.
- 341. How often do we perm Self Audits? Field: Enter how often you do Self-Audits.
- 342. Attach Self Audit Field: You can attach your own self audit checklist or print the blank self-audit checklist that comes with FSP!
- 343. What is our stunning procedure? Field: Enter a detailed description of your stunning procedure.
- 344. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.
- 345. What is our procedure for inclement weather Field: Enter a detailed description of your procedures for dealing with inclement weather.
- 346. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.
- 347. How often do we check animals that are kept overnight? Field: Enter a detailed description of your animal checks (Overnight).
- 348. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.



349. Who provides our Humane Handling Training Curriculum? Field: Enter a detailed description of your Humane handling training curriculum.
350. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.
351. What is our procedure for a miss-stun? Field: Enter a detailed description of your procedures for a miss-stun.
352. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.
353. What is our procedure for dealing with the disabled? Field: Enter a detailed description of your procedures for handling slow animals/downers.
354. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.
355. Are we audited by a third party, if so attach the latest audit Field: Enter a detailed description of your latest third party audit.
356. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the documents from your third party audit.
357. How often do our employees receive refresher training? Field: Enter a detailed description of how often your employees receive refresher training concerning humane handling.
358. Attach Documents Field: In the document library (Attach documents) click on the library icon, click "+" button and navigate to the place on your computer where you have stored the file, highlight the file and click open. Repeat until you have added all of the supporting documents that you used to in your decision process.
359. Click Save and Next.
360. The next three pages are the built in version of the humane handling self-audit; they system will not allow you to use them on a tab or your phone unless you have the L3 or L4 versions.
361. Click save and next and you will be brought back to the main screen.
362. Sign Field: Sign the humane handling program by having the person with the authority to sign it click the sign button. Please note that the person who signs it will need to be logged into FSP!



363. Click Exit Human Handling Program.

Poultry Good Commercial Practices:

- 364. Click the Poultry GCP button on the main left navigation screen.
- 365. Date Prepared Field: Enter the date prepared.
- 366. Prepared By Field: Select the person who prepared the document.
- 367. Effective Date Field: Enter the effective date.
- 368. Reason Modified / Reassessed Field: Enter the reason the plan has been modified/reassessed.
- 369. How often do employees who handle animal receive animal training? Field: Enter how often employees receive animal handling training.
- 370. Who performs the training? Field: Enter the person who conducts the training
- 371. Who / where was the curriculum developed? Field: Enter the developer of the training.
- 372. Emergency Response and Recovery GMP States Field: Enter a brief description of your emergency response and recovery GMP.
- 373. GMP Field: Select your Emergency Response GMP.
- 374. If you don't have an emergency response and recovery GMP you can create one by clicking on "create GMP".
- 375. Answer the next three questions by checking yes, no, or N/A.
- 376. What is our policy about loose birds? Field: Describe your loose bird policy.
- 377. Click Save and Next
- 378. Our holding times are kept to a minimum unless an unforeseen event occurs field: Select yes or no to your holding times. Enter comments concerning your holding times.
- 379. How do we track DOA's and document the number? Field: Enter the procedure you use to track DOA's. (Dead on Arrival)
- 380. What % of daily DO's trigger corrective actions? Field: Enter the percentage of DOA's that it takes to trigger corrective actions.
- 381. Answer the next two questions by selecting the appropriate box, make appropriate comments about the subject in the comments box.
- 382. How often are coops inspected Field: Enter how often you inspect coops, daily, per load, weekly, etc.
- 383. Answer the next two questions by selecting the appropriate box, make appropriate comments about the subject in the comments box.



- 384. How are birds protected from extreme cold and heat? Field: Describe how you protect the birds from extremes of heat and cold.
- 385. If for some reason we cannot process all our birds our plan on how to handle them is to Field: Describe how you deal with extended power outages, equipment breakdowns.
- 386. How do we keep feed and water withdrawal to the minimum? Field: Describe you water and feed withdrawal programs.
- 387. How do we assure that unloading is conducted in a manner as not to injure birds? Field: Describe your unloading procedures.
- 388. Answer the next two questions by selecting the appropriate check box, make appropriate comments about the subject in the comments box.
- 389. How are stunning and processing equipment monitored to insure proper functioning for humane processing field: Describe your monitoring procedures for your stunning equipment.
- 390. How do we verify that birds are insensible to pain when euthanized field: Describe how you verify birds are insensible to pain when euthanized.
- 391. Select yes or no to automatic knife use and describe details if you do use them such as voltage/amp requirements.
- 392. If we use an automatic knife how do we verify that is at least 98% effective? Field: Describe how you verify the effectiveness if you use an automatic knife.
- 393. Click Save and Next.
- 394. Select yes or no to back up personnel and briefly comment about their placement and how they function.
- 395. Select yes or no to the question of verifying that all birds are dead prior to entering the scalding, make comments in reference to how you do this.
- 396. Broken wings and legs are monitored at the following location field: Describe the location and procedure for monitoring broken legs and wings.
- 397. At what level do we take corrective actions if broken or dislocated wings are observed? Field: Describe the action level (% of birds) of broken or dislocated wings that are observed.
- 398. We euthanize any live birds that are culled at the plant by Field: Select the way you euthanize cull birds, please note industry terms are head removal=rapid decapitation, ringing the neck=rapid cervical disarticulation, gassed=gassing with nitrogen, etc.
- 399. Additional Information concerning our Poultry Good Commercial Practices Field: Enter any additional information concerning your poultry good commercial practices.
- 400. Click save and next
- 401. Sign Field: Click the "sign" button and the person with overall authority to sign is selected. Please note that the person with authority to sign must be logged into FSP!
- 402. Select the name of the person who is signing and click sign.
- 403. Click exit poultry GCP.



Product Trace Back:

404. Select Product Trace-Back from the main left hand navigation menu.
405. Prepared By Field: Enter the person who has prepared this document.
406. Written Plan Field: If you have a written plan click the "+" button and navigate to it, highlight it, and click open.
407. Trace-Back Written Plan Documents Field: If you have Trace-Back written documents attach them by clicking the "+" button and navigate to it, select it, and click open. Repeat until all of your documents are attached.
408. Selected GMP Field: In the receiving tab select you're receiving GMP/prerequisite program using the down arrow.
409. Receiving Record Field: Attach your blank receiving record. If you don't have one you can use the one that comes with FSP!
410. The receiving records buttons will work however they will not integrate in FSP! L1.
411. Selected GMP Field: In the batching tab select your batching GMP/prerequisite program using the down arrow.
412. Batching Record Field: Attach you blank batching record. If you don't have one you can use the one that comes with FSP!
413. The batching records buttons will work however they will not integrate in FSP! L1.
414. Selected GMP Field: In the shipping tab select your shipping GMP/prerequisite program using the down arrow.
415. Shipping Record Field: Attach you blank shipping record. If you don't have one you can use the one that comes with FSP!
416. The shipping records buttons will work however they will not integrate in FSP! L1.
417. Selected GMP Field: In the Spillage / waste tab select your inedible GMP/prerequisite program using the down arrow.
418. Inedible Record Field: Attach you blank inedible record. If you don't have one you can use the one that comes with FSP!
419. The Inedible records buttons will work however they will not integrate in FSP! L1.
420. Sign Field: Click the "sign" button. When the pop up opens up the person with the authority to sign selects their name and clicks save. Please note that this person must be signed in to FSP!
421. We have provided a word document in the supporting documents folder called "TraceBack" that you can use to create your Trace-Back Program, we recommend that it be done as four separate GMP's. In FSP! L3 these are automated.
422. Click Exit Trace Back button at the bottom of the page.



Recall Management:

- 423. Next select Recall Management from the main left navigation menu.
- 424. Date Prepared Field: Enter the date prepared.
- 425. Prepared By Field: Enter the person who prepared this program.
- 426. Effective Date Field: Enter the effective date for the program.
- 427. Who is our Recall Coordinator Field: Select the Recall Coordinator, enter his/her cell phone and email.
- 428. Backup Recall Coordinator Field: Select the backup recall coordinator, enter his/her cell phone and email.
- 429. Mgr With Recall Authority Field: Select the person with the authority to initiate a recall, enter his/her cell phone number and email.
- 430. Employee's on Recall Team Field: Click the "+" button to add the members to the recall team. In the pop up enter their name, phone number, email address, and fax number. Click save team member and repeat until all members have been added.
- 431. Consultants or other experts that will be used to assist with recalls Fields: Click the "+" button to add outside experts that will assist you during a recall. Enter their information and click save.
- 432. Media Outlets Fields: Click the "+" button to add media outlets, enter the contacts information and click save.
- 433. Federal and State Agency personnel who will be notified in the event of a recall Field: Add regulatory agency personnel that must be notified, links to determine who your local contact is provided. Add by clicking the "+" button and adding them.
- 434. Click Save and Next.
- 435. If you are regulated by the USDA stay on the USDA tab, if you are regulated by the FDA select the FDA Tab.
- 436. Launch USDA Recall Plan Field: In the USDA tab select if you want to use the USDA recall plan. If you do you can launch it either to view or to print.
- 437. Upload Recall Plan Documents Field: Click the "+" button to upload recall plan documents.
- 438. You can type in additional information that will print at the header of the FSP! recall plan.
- 439. Click Save.
- 440. In the FODA tab select if you want to use the FDA recall plan. If you do you can launch it either to view or to print.
- 441. Click the "+" button to upload recall plan documents.
- 442. You can type in additional information that will print at the header of the FSP! recall plan.
- 443. Click Save.



- 444. Sign Field: Click the “sign” button, in the pop up window select the person with authority to implement this program. Please realize that the person must be signed in to FSP!, then click sign.
- 445. Click Exit Recall Management.

System Administration:

- 446. Select System Administration button in the main left hand navigation menu.
- 447. In the opening screen you can turn on and off Show Ads and show help buttons by selecting the check box.
- 448. You can upload your logo.
- 449. Click the authorized Users tab at the top.
- 450. Here you can add users by clicking “+” button to bring the pop up screen that allows you to add users.
- 451. To subtract users highlight the user and click the “-” button.
- 452. All other fields are pre-filled or are for use in the L3 and L4 versions.
- 453. Click the exit system administration menu.

Food Safety Validation:

- 454. Click the validation button on the main left menu.
- 455. In the select plan area select the plan you wish to prepare validation for. (For HACCP plans you will see a second menu that allows you to select the specific process step to validate.)
- 456. Click the “add initial validation plan” button.
- 457. Using the “+” button add supporting documents that are used in the validation process.
- 458. Check Yes or No if this document is directly related to our process.
- 459. Check yes, no, or N/A if this is a challenge study validation.
- 460. If it is a challenge study click the “+” button to add the challenge study documents (procedures, protocols, letters of approval, etc.)
- 461. Enter the hazard of concern, be specific such as E.coli 0157:H7, Metal fragments greater than .7 MM, etc.
- 462. Enter the product you are using for validation, remember to select the product with the highest risk, such as hot dogs for RTE/LM instead of a shelf stable sausage.



463. Enter a descriptive narrative of the protocol you are using to validate the process, please remember to include the critical parameter that you are validating, we strongly recommend that you state it in the first sentence.
464. Skip down to the Prepared on field and enter the date it was prepared.
465. Enter the person who prepared the validation protocol.
466. Select the person with authority to sign this plan.
467. Click the “activate plan button. “
468. Click the Save button. The plan is now active.
469. Come back into the plan after you have completed the validation period.
470. Enter the summary of your findings, be detailed and descriptive.
471. Enter your final determination, is the plan valid or not.
472. Attach the records (all records) associated and generated with the validation protocol.
473. Go to the plan complete field and select the person with the authority to sign the plan.
474. Click “Complete plan”.
475. Click save.
476. Click the “add ongoing validation plan” button.
477. Using the “+” button add supporting documents that are used in the validation process.
478. Check Yes or No if this document is directly related to our process.
479. Check yes, no, or N/A if this is a challenge study validation.
480. If it is a challenge study click the “+” button to add the challenge study documents (procedures, protocols, letters of approval, etc.)
481. Enter the hazard of concern, be specific such as E.coli 0157:H7, Metal fragments greater than .7 MM, etc.
482. Enter the product you are using for validation, remember to select the product with the highest risk, such as hot dogs for RTE/LM instead of a shelf stable sausage.
483. Enter a descriptive narrative of the protocol you are using to validate the process.
484. Skip down to the Prepared on field and enter the date it was prepared.
485. Enter the person who prepared the validation protocol.
486. Select the person with authority to sign this plan.
487. Click the “activate plan button. “
488. Click the Save button. The plan is now active.
489. Come back into the plan after you have completed the validation period.
490. Enter the summary of your findings, be detailed and descriptive.
491. Enter your final determination, is the plan valid or not.
492. Attach the records (all records) associated and generated with the validation protocol.
493. Go to the plan complete field and select the person with the authority to sign the plan.
494. Click “Complete plan”.



495. Click save.
496. Click the System Administration button on the left main navigation menu.
497. This is the information captured when you set up FSP!, you can edit the information and then click save. Please note that the "Show Ads" button is turned off. If you wish to receive notices, announcements about upgrades, and offers from our allied business's you can check this box and they will display in the main screen, the system will need to be connected to the internet for this option to function. Also, the show help buttons is displayed, this is not active however it will be turned on in the upcoming maintenance update.
498. Click authorized users tab at the top of the screen.
499. To add a user click the "+" button. To remove a user click on the user and select the "-" button.
500. The basic instructions for adding a user on step 13 apply.

Again, thank you for purchasing FSP!, if we can assist you in any way please don't hesitate to contact us. We will be adding maintenance updates to the software that will be based on your feedback! If there is a form you think would be useful, or a function that needs to be simplified don't hesitate to contact us at support@dkmiss.com!



Refresher HACCP Training for FSP! L1

So what is HACCP?

HACCP is a systematic approach to the identification, evaluation, and control of production hazards based on seven principles. While it is primarily a system used in the food industry, it is also used by other industries worldwide. The acronym stands for Hazard Analysis and Critical Control Point. The system was developed in the 1950's and 1960's by Pillsbury, NASA, and the US Army to make sure food was safe.

HACCP is an evolving system. In the United States, there are two regulatory authorities that mandate HACCP for the production of certain products. The USDA FSIS mandates HACCP for the products produced under the Federal Meat Inspection Act and the Poultry Inspection Act and the FDA mandates HACCP for the production of juice products. Please note that the majority of food producers utilize HACCP; however, what is required of them under the regulations varies.

HACCP is also part of two other larger systems, ISO 22000 and Integrated Food Safety Systems.

HACCP PRINCIPLES

- Principle 1: Conduct a hazard analysis.
- Principle 2: Determine the critical control points (CCPs).
- Principle 3: Establish critical limits.
- Principle 4: Establish monitoring procedures.
- Principle 5: Establish corrective actions.
- Principle 6: Establish verification procedures.
- Principle 7: Establish record-keeping and documentation procedures.

We are going to go through the process of developing a HACCP system based on the USDA FSIS and FDA models.

Preliminary Steps to utilizing HACCP:

HACCP experts believe that a company will do a better job of HACCP plan development if it takes some preliminary steps before it attempts to apply the seven principles and write a plan.

Take the following steps to get started:



1. Assemble the HACCP team, including one person (consultant, employee, or other resource) who is HACCP-trained.
2. Describe the product and its method of production and distribution; identify the intended use and consumers of the products.
3. Develop and verify process flow diagram(s).

Assemble the HACCP team, including one person who is HACCP-trained.

HACCP system development is one of those tasks that is probably better done by more than one person, even in a very small company. HACCP is an overall process control system and it takes a variety of different kinds of knowledge and experience to develop a good system. If your company has only a few people in it, they may all need to be on the HACCP team, because they all probably have multiple roles and responsibilities in the company's operations. You should consider including on your HACCP team, some resources which may be outside your company.

Describe the product and its method of production and distribution; identify the intended use and consumers of the products.

The next preliminary step to take is to have the HACCP team describe the product(s) and their methods of production and distribution. The important thing for them to keep in mind is that they need to include every step in the process.

The following questions should be answered when you describe the product:

1. What is the common name of the product?
2. How is the product to be used?
3. What type of packaging encloses the product?
4. What is the length of shelf life of the product, at what temperature?
5. Where will the product be sold? Who is the intended consumer and what is the intended use?*
6. What labeling instructions are needed?
7. Is special distribution control needed?

* Regulatory requirement for USDA FSIS inspected facilities.

After your team has described the products, they can move on to the next preliminary step.

Develop and verify process flow diagram(s).



A flow diagram is a simple schematic picture of the process you use in your plant to produce the product. It needs to be an accurate, clear sketch of the process used in your plant to make the product.

The best means to make sure your flow diagram is accurate is to have the HACCP team verify it by walking through the plant and making sure all the steps in the process you carry out are included in the flow diagram. It is also a common means by which auditors or inspectors verify that a particular flow diagram is correct and complete.

When you are certain that you have an accurate flow diagram and your team has verified it, you have completed the preliminary steps that will prepare you for HACCP system development. It is time for your team to apply the seven principles of HACCP and develop your HACCP plan.

PRINCIPLE I: CONDUCT A HAZARD ANALYSIS

The first principle of HACCP is to conduct a hazard analysis.

Conducting a hazard analysis is generally considered to be a two-step process. The first step is to identify the threats to human health which might be introduced into food products as those products are produced. These hazards are usually grouped into three categories: Biological (including microbiological), Chemical, and Physical. The FDA requires a fourth category, Radiological.

1. Biological Hazards

Biological hazards are living organisms that can make food unsafe to eat. Biological hazards may be bacterial, parasitic, or viral. Biological hazards are frequently associated with the raw materials from which meat and poultry products are made, including the animals and birds, which are primary components. However, biological hazards may be introduced during the processing of meat and poultry products: from the people who are involved in the processing; from the environment in which the foods are processed; from other ingredients in the products; or from the processes themselves. Identifying the biological hazards to which your production processes might be subjected is clearly a difficult and important task—one that requires all the expertise that your HACCP team can bring to it. Currently, there is a great deal of emphasis on microbial hazards associated with meat and poultry products. Some of the major pathogens that may be associated with meat and poultry products are: *Salmonella*, *Campylobacter jejuni*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Clostridium botulinum*, *Staphylococcus aureus*, and *Yersinia enterocolitica*.^[AL1]

2. Chemical Hazards



Chemical hazards may be the result of something naturally occurring in foods or added during the processing of foods. Harmful chemicals have been associated with both acute cases of foodborne illness and chronic illness.

Naturally occurring chemical hazards are those that are natural constituents of foods and not the result of environmental, industrial, or other contamination. They include aflatoxins, mycotoxins and shellfish toxins.

Added chemical hazards are those which are intentionally or sometimes unintentionally added to food during the growing, harvesting, storage, processing, packaging, or distribution phases of production. This group of chemical hazards is very broad and might include components of animal feed or drinking water, animal drugs, pesticides, food ingredients, or chemicals used in the processing establishment such as lubricants, cleaners, paints, and coatings.

3. Physical Hazards

A physical hazard is a physical component of a food that is unexpected and may cause illness or injury to the person consuming the food. Foreign materials such as glass, metal, or plastic are familiar physical hazards in meat and poultry products, usually found because a process or a piece of equipment has not been properly controlled while the food was being produced.

Radiological Hazards:

A radiological hazard is typically exposure through ingestion or exposure through environment. Ingestion is the risk if the product has a radiological source in it. For example, some grains grown in contaminated soil pick up the isotope and store it. When a person or animal eats that isotope, it can cause cancer, radiation poisoning, etc. There are locations throughout the world where the soil is naturally contaminated and products produced on them may or may not also be contaminated. Exposures to environmental sources are typically associated with natural disasters that expose the radiation source and contaminate the product, ingredient, animal, or human. For example, when the power plants in Japan failed due to the tsunami, the radioactive water contaminated product packaging, people, and animals in the near proximity and they became ill from the radiation. While radiological hazards are real and the results of exposure can be devastating, they are very rare.

There are a number of situations that can contribute to physical hazards in foods. They include: contaminated raw materials; poorly designed or poorly maintained facilities and equipment; contaminated packaging materials; and inattention to details by employees with key responsibilities.

This first step in identifying hazards which might be associated with your production process might be considered like a “brainstorming” session. Your HACCP team should use the flow diagram and product description, which you created in your preliminary steps, and systematically think about what could occur at each step in the process.



The second step in performing a hazard analysis is to identify preventive measures that could be used to control each hazard. Preventive measures are the physical, chemical, or other means that can be used to control a food safety hazard. More than one preventive measure may be needed to control a food safety hazard and more than one food safety hazard may be controlled by a specific preventive measure.

It is critical that the hazard analysis is done correctly. This is often a difficult and time-consuming step, and one that requires all the various technical and scientific resources you can obtain. Doing a good job and taking your time here is worth the effort. You cannot expect to develop a good HACCP system if you have not been careful and thorough in your hazard analysis.

PRINCIPLE II: IDENTIFY THE CRITICAL CONTROL POINTS

The second HACCP principle is to identify the critical control points (CCPs) in the process. A CCP is a point, step, or procedure in a process at which control can be applied and, as a result, a hazard can be prevented, eliminated, or reduced to acceptable levels.

So far, in developing the HACCP plan, your HACCP team has identified biological, chemical, and physical hazards in the raw materials and the ingredients you use as well as in the steps of your process. For each safety hazard reasonably likely to occur, you have identified a preventive measure.

Your next step is to find the point or points in the process where these preventive measures should be applied.

The location of your Critical Control Points is vitally important. The location in your process must be well thought out and defensible. An example is allergens in product. It is critical that you know what products have been exposed to allergens. Having a CCP at the end of the process without knowing what products have been exposed fails to make sense, there is no control at the end of the process. Instead, the CCP should be at the adding ingredient step where every product that has an allergen added, or is exposed to an allergen, is labeled appropriately.

PRINCIPLE III: ESTABLISH CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT

HACCP principle three instructs your team to establish critical limits for each preventive measure you will carry out at each CCP. This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. The USDA FSIS defines a critical limit as: the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified hazard.



Critical limits are the boundaries of safety for preventive measures put in place at CCPs. A critical limit will usually be a reading or observation such as a temperature, a time, a product property such as water activity, or a chemical property such as available chlorine, salt concentration, or pH. Critical limits need to be exact and specific.

When deciding what your critical limits should be, there are several sources to consider. First are the regulatory requirements which apply to your processes. These must be met. For example, if you produce cooked beef products, you must have critical limits that meet the current FSIS regulatory requirements for those products. If you produce fresh shell eggs, you must meet the FDA temperature requirements. There may be other sources of critical limits, such as the times and temperatures that you use in making the products you produce. In any case, you need to establish a critical limit for each preventive measure you intend to apply at your CCPs.

There are two types of critical limits. A critical limit can be an *upper limit* where a set amount or level cannot be exceeded. A critical limit can also be a *lower limit* where a minimum amount is required to produce the safe effect. To address the hazard in ground product of metal fragments from the grinding equipment, the *upper* critical limit for the preventive measure could be no sharp metal fragments more than 1/32 inch. A grinding room temperature of 50° F to help control pathogen growth is another kind of *upper* critical limit. An example of a *lower* critical limit would be the addition of an acidifier to inhibit bacterial growth.

PRINCIPLE IV: ESTABLISH MONITORING PROCEDURES

To carry out HACCP principle four, your team needs to establish monitoring procedures. Monitoring procedures are those things which are done routinely, either by employee or by mechanical means, measure the process at a given CCP. The key is that they create a record. Some monitoring procedures are employee observations or checks, such as checking the documentation accompanying incoming materials. Some monitoring procedures are records from instruments, such as recording thermometers.

Continuous monitoring is always preferred when it is feasible. When it is not possible, your HACCP team will need to decide what will be their non-continuous monitoring procedures and how frequently they will be performed. There are several issues to consider when deciding the frequency of non-continuous monitoring checks; the most important is that the procedures must be performed sufficiently often to accurately reflect that the process is under control. Expert advice from people with knowledge of practical statistics and statistical process control will be important in making your decisions about frequency.



Another factor that HACCP teams must consider is the capacity of the plant to take corrective actions when monitoring procedures reveal that there have been deviations from critical limits. When monitoring procedures show that there has been a deviation from a critical limit, corrective actions need to be applied to all the potentially noncomplying product. This usually includes all of the product produced since the time of the last successful monitoring procedure result. So, if your monitoring procedure was to perform a physical check on arriving product, and your team decided to do this only once per shift, a deviation from the critical limit would mean that you needed to apply corrective actions to all the product which had arrived during that shift.

Another matter for your HACCP team to consider when they are deciding on what should be the monitoring procedures and how frequently they should be performed is the need for rapid, real time feedback. Generally, physical and chemical procedures are preferred over microbial approaches for monitoring because they provide more rapid feedback.

Monitoring procedures need to be well planned and effective because of the potentially serious consequences of loss of control. Employees monitoring CCPs should be trained in the technique (the monitoring procedure) to be used to monitor each preventive measure or control. They should fully understand the purpose and importance of monitoring and accurately report monitoring activities and results. They must have complete access to the CCP being monitored and to the process-monitoring instruments being used.

The people performing monitoring must record exact values where exact values are indicated, not “yes/no” or “OK” observations. This means that if the critical limit is a minimum internal temperature of 160° F, the observations on the monitoring record would be recorded as “162 °F,” “163°F” rather than “yes” or “OK.” Another example might be if a certificate of analysis is required for each incoming load of raw material that the specific criteria that it was tested for, such as 100% High Density Polyethylene. The record should indicate “100% Polyethylene received” and not “ok.”

PRINCIPLE V: ESTABLISH CORRECTIVE ACTIONS

HACCP principle five says: Establish corrective actions to be taken when monitoring shows that there is a deviation from a critical limit. USDA FSIS regulation 9 CFR 417.3 identifies the four features of corrective actions that FSIS regulators will be checking. They are:

1. Has the cause of the deviation been identified and eliminated?
2. Will the CCP be under control after the corrective action has been taken?
3. Have measures to prevent recurrence of the deviation been established?
4. Do the corrective action procedures make sure that no product, which is injurious to health or otherwise adulterated because of the deviation enters commerce?

The FDA has a more extensive list:



(a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation; and

(5) Perform or obtain timely verification in accordance with §120.11, by an individual or individuals who have been trained in accordance with §120.13, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §120.11(a)(1)(iv)(B) and the recordkeeping requirements of §120.12.

While the FDA set looks to be much more extensive, it is really the same requirement.

HACCP is a preventive system to correct problems before they affect the safety of the food products people or animals actually consume. Deviations from critical limits will occur; therefore, you need to have a plan to make sure those deviations do not lead to unsafe products. Planned corrective actions are the way you do this. Your HACCP team needs to understand how important it is to carefully carry out this principle. The problem is that if you have a very well designed and implemented system you won't be able to know what those deviations are as you will have already covered them, the key is to make sure your employees follow the regulatory requirements, that if there is a deviation they know exactly what they need to do to stop the product from entering commerce!



For each CCP, your team needs to devise a standardized set of actions that company employees will follow when there is a deviation from a critical limit. These are some questions they might ask in developing corrective actions:

How will people be informed when the deviation occurs? If a person is performing the monitoring procedure, who will that person contact?

Who will be responsible for controlling the product that may have been affected by the deviation?

How should that person decide how much product needs to be controlled?

Who will be involved in deciding what to do about the product which might have been affected by the deviation?

How will we decide what was the cause of the deviation? If we need technical experts outside the company, how do we get them?

Once we have figured out what was the cause of the deviation, who will be involved in deciding how to get the process back in control and prevent recurrence of the deviation?

If our HACCP trained individual is not available in the plant immediately, how can we get HACCP expertise to help decide if our plan needs to be modified?

Who in the company needs to sign off on any modifications to our plan?

Who will be responsible for keeping the records of everything we do in response to a deviation from a critical limit at this CCP?

If any person who has a responsibility in our corrective action plan is not available, who will be the back-up?

Is this set of corrective actions feasible at all times?

PRINCIPLE VI: ESTABLISH RECORDKEEPING PROCEDURES

HACCP principle number 6 is to establish effective recordkeeping procedures that document the HACCP system. The regulatory recordkeeping requirements for both the USDA and FDA are quite comprehensive. Your team should review them carefully. At a minimum, it is recommended that all records be maintained for a minimum of two years. All validation data should be kept indefinitely.



Recordkeeping is an essential feature of a HACCP system and must be planned and carried out as carefully as any other element. This principle requires the development and maintenance of records about both plan development and the operation of the system.

One way to approach development of the recordkeeping requirements of your HACCP system is to review the records you already keep and see if they are suitable, in their present form or with minor modifications, to serve the purposes of your HACCP system. The best recordkeeping system is usually the simplest one that can be easily integrated into the existing operation.

When you are setting up your recordkeeping system, think about who will be in the best position to make the record entry, who will need to review the record prior to shipping, and when and where will be the best place to keep the records. Think about making simple understandable forms that will work well in your situation. Make sure your employees know exactly what is expected if they are responsible for making a record entry. It is extremely important that they sign and date the records at the time the specific event occurs.

PRINCIPLE VII: ESTABLISH VERIFICATION PROCEDURES

HACCP principle seven is to establish verification procedures to make sure the plan is working correctly.

Your team needs to decide on what procedures the plant will perform to verify that the HACCP system is working effectively *and* how often these actions will be performed. Verification uses methods, procedures, or tests in addition to those used in monitoring to see whether the HACCP system is in compliance with the HACCP plan or whether the HACCP plan needs modification. There are three types of verification.

Validation is the initial phase in which the plan is tested and reviewed. The choices made while working through the preliminary steps and HACCP principles must be repeatedly tested and shown to prevent or control identified hazards in the “real world.” In this phase, microbial, residue, or chemical testing can be used effectively to verify that the process is in control and is producing acceptable product. Such testing provides clear evidence that the techniques and methods adopted by the plant to control hazards are not just effective in theory but will work in *this* specific plant.

Ongoing Verification ensures that the HACCP plan is working effectively on a day-to-day basis. This type of verification includes such tasks as calibrating monitoring instruments, observing monitoring activities and corrective actions, and reviewing HACCP records to see that they are being made and kept according to the plan.

Reassessment is an overall review of the plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Reassessment is similar to validation in that it considers whether the plan is adequate in general rather than focusing on the plan's daily operations. It is also similar to



validation in that it must be done by a HACCP-trained person. USDA FSIS requires that a reassessment must be performed at least annually.

Another way to think about it is this: You validate that your plan is the right plan for your system, you monitor it so that you know what it is finding, you verify that you are implementing it correctly, and you reassess it anytime there is a change.

Before we go any further, please review some of the definitions we are going to use:

DEFINITIONS

CCP Decision Tree:

A sequence of questions to assist in determining whether a control point is a CCP.

Control:

(a) To manage the conditions of an operation to maintain compliance with established criteria.

(b) The state where correct procedures are being followed and criteria are being met.

Control Measure:

Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Control Point:

Any step at which biological, chemical, or physical factors can be controlled.

Corrective Action:

Procedures followed when a deviation occurs.

Criterion:

A requirement on which a judgment or decision can be based.

Critical Control Point:

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit:

A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Deviation:

Failure to meet a critical limit.

HACCP:

A systematic approach to the identification, evaluation, and control of food safety hazards.

HACCP Plan:

The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP System:

The result of the implementation of the HACCP Plan.

HACCP Team:



The group of people who are responsible for developing, implementing and maintaining the HACCP system.

Hazard:

A biological, chemical, physical, radiological agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis:

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Monitor:

To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Prerequisite Programs:

Procedures, including Good Manufacturing Practices, which address operational conditions providing the foundation for the HACCP system.

Severity:

The seriousness of the effect(s) of a hazard.

Step:

A point, procedure, operation, or stage in the food system from primary production to final consumption.

Validation:

That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification:

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

Practical exercise: Let's get started!

As we said earlier: HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, radiological, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution, and consumption of the finished product.

If HACCP is going to work in your facility, everyone must be strongly committed to it, from your CEO to the production employee on the floor.

So how do we actually implement HACCP? We start by looking at what we do and then analyzing it for hazards (Conducting a Hazard Analysis).

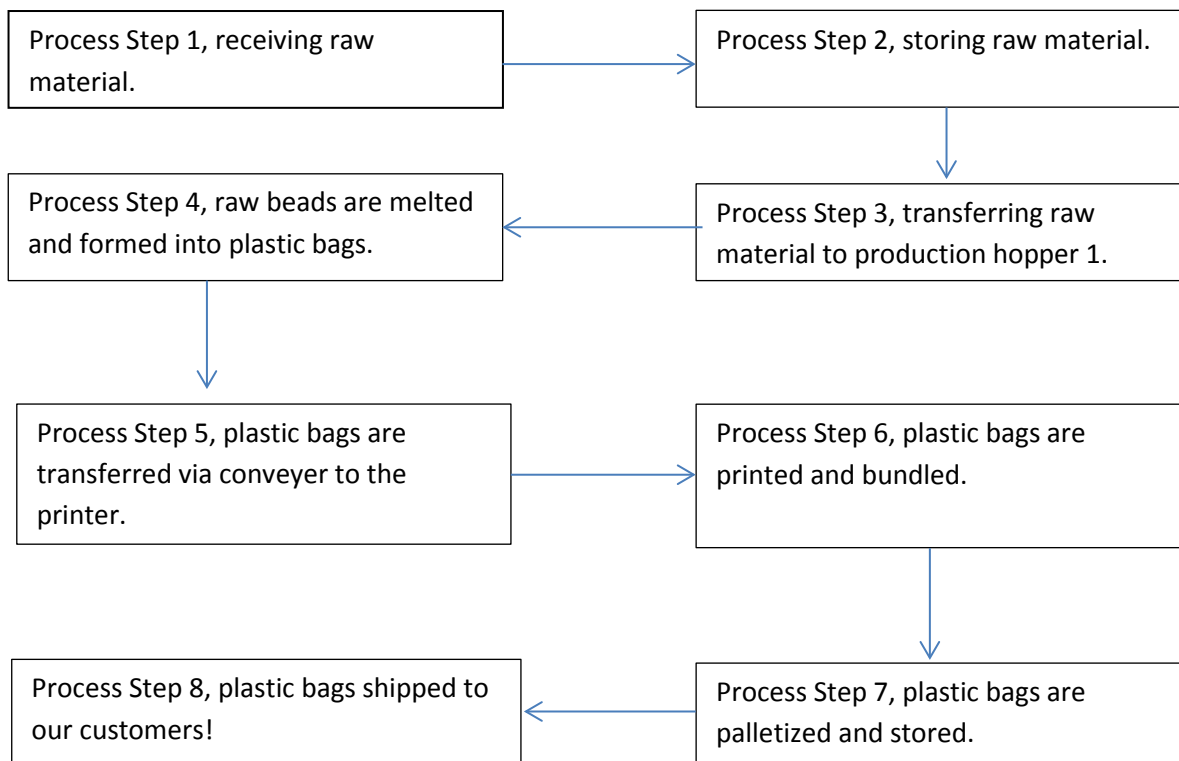
What is it that we make? Plastic Bread Bags.



Who uses it? Our bakery clients

How do they use it? They load the bags into their packaging machine. They are then stuffed with the bread, tied with a plastic tie, shipped to retail stores, and sold to the general public.

Your team develops the flow diagram of your facility, for example:



(Please note that this example does not include all steps or potential hazards in this production process and is merely being used as an example to demonstrate the thought process)

Now that you have a flow diagram, each step is assessed for hazards and things that could go wrong with the process. Because we are making a product that will come in direct contact with food, we need to look at the four categories associated with food: Chemical, Physical, Radiological, and Biological for each step.

At process step one, we review our process for Biological hazards. We can't think of any and our experts determine that, because of our process, there are none. For Physical hazards and

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Radiological hazards, we again can't think of any and neither can our outside experts. When they reviewed our receiving records, there were never any physical or biological hazards identified. There is nothing to show a radiological hazard and we can't identify any place in the system where one would be introduced. When we looked at Chemical hazards, we can't think of any either. The raw material is plastic. Someone asks about that time we got the new supplier, they had the PST produced plastics, and we had to throw the whole lot out because it wasn't food grade. After some discussion, you determine you have a potential chemical hazard.

Next you ask, is it likely to occur? You determine that it is not very probable for it to happen; however, if it did, the results would be catastrophic. People could die from eating the bread! So while the probability isn't high, the fact that it has occurred and might again if you don't watch for it tells your team that this is a critical step in your process. In fact, it is the critical control point in your process to control the composition of your product!

The next question is how do you control this? You determine that the only way to control it is to require that your suppliers provide you with 100% High Density Polyethylene.

Then you think, how will I know that it's really High Density Polyethylene? How do I monitor this critical limit? You determine that you must receive a certificate of analysis showing that the product is High Density Polyethylene for each load and that the person receiving the load will verify the certificate before receiving it into your storage silos.

What happens if something goes wrong and they ship you something other than High Density Polyethylene? You decide that you will take the following steps:

- 1) Verify that you ordered High Density Polyethylene, assuming you did ask them why they shipped this to you.
- 2) Reject the load back to your supplier without putting it in the silo.
- 3) Double check the certificate of analysis from the previous shipment from this supplier.
- 4) Change suppliers.

Now you need to be able to figure out how you are going to validate and verify that your system is working at this point. To validate your system, you decide that you are going to send off samples from the first five shipments from each supplier every year to a laboratory for testing to verify their composition. To verify that you are implementing your program, you are going to do a direct observation of the employee who is responsible for checking the certificate of analysis for each load once a week to make sure he or she is actually checking them before offloading.

The last thing you need to do at this step is figure out how you are going to record everything you are doing. You develop a simple record keeping log for the employee on the receiving dock. Every time he or she receives a load, they open the paper work and review the certificate of



analysis. They write down the analysis findings, sign it, and date it. They then attach the certificate to the form. You also make a block for the QA manager to verify that the operator has checked it correctly. It also includes blocks for signing and dating. The final thing you do is set up a file system where you will keep the paperwork as well as the laboratory results you get from your verification samples. You also designate the QA manager to review all the paperwork once a month as an added verification step.

You then review the rest of your process steps and can't find any other process steps that have any hazards.

Then one of the team members asks if the daily clean-up program or the pest control program should be added to this. After all, if the plant is dirty or there are rodents running all over the plastic bags, they shouldn't be used to store bread. After some thought you determine no, those are really your pre-requisite programs, and while they support that your product is safe to use as a food container, they really aren't part of the HACCP Plan, they actually support it.

You then decide that while you don't plan on getting any new equipment or employees, you will reassess the HACCP plan every year just to make sure nothing has changed.

The final thing you decide to do is make sure that before you ship any product that you perform a pre-shipment review of all documentation that you have to make sure each and every shipment is safe. You designate the QA manager to perform this and put controls in place in your shipping program that will stop a shipment from going out if it hasn't gone through the pre-shipment process. You determine you will look at the HACCP Paperwork, your clean up paperwork, and your pest control paperwork at a minimum.

You put your plan in place, train the employees who are implementing it, and review your records. You are all set to go!

The key point to remember with HACCP: *HACCP is a management system in which food safety is addressed through the analysis and control of biological, radiological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing a safe product!*

Congratulations, you have now gone through the basics of HACCP!

This training has been developed utilizing US Federal Government Guidelines for basic HACCP compliance. It is strongly encouraged that all employees on the HACCP Team review this information prior to developing a food safety program. Utilizing Food Safe Pro! along with this training will enable you to quickly and systematically develop your food safety program. For more information please contact us at info@werfoodsafety.com